(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) Publication number: **0 161 865**
A2

(12) EUROPEAN PATENT APPLICATION

(21) Application number: 85303083.1

(22) Date of filing: 01.05.85

(51) Int. Cl.⁴: A 61 F 13/02

(30) Priority: 03.05.84 GB 8411368
23.05.84 GB 8413231

(43) Date of publication of application: 21.11.85
Bulletin 85/47

(84) Designated Contracting States: BE CH DE FR IT LI NL SE

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(54) Adhesive wound dressing.

(57) An adhesive wound dressing which comprises a flexible polymer film having an adhesive surface and a non-adhesive surface on the opposite side, a removable protector over the adhesive surface and a detachable handle along an edge margin of the polymer film is described. The handle is used to facilitate handling of the film during application of the dressing and is formed from a tearable material so that it can be removed by tearing without disturbing the applied dressing. In a second described embodiment the tearable handle carries an adhesive coating so that the user has the option of removing the handle or adhering it to the skin of the patient.

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ADHESIVE WOUND DRESSINGS

The present invention relates to adhesive wound dressings and processes for their manufacture and use.

Conventional adhesive wound dressings usually comprise an adhesive coated sheet with a removable protector over the adhesive coating. The application of these wound dressings to a patient can be achieved by removing the protector from the adhesive sheet and adhering the sheet to a patient's skin at the wound site. Such dressings must be sufficiently conformable to allow the dressing to be worn in comfort by the patient and not to become dislodged by movement of the patient. The sheet used in these dressings is conventionally a thin elastomeric film. When coated with adhesive this flexible film can be difficult to handle during its application to a patient resulting in the dressing creasing or puckering or otherwise self-adhering. In one way of overcoming this problem the flexible adhesive coated sheet of such conformable dressings can have one or more non-adhesive handles at an edge or edges thereof to facilitate handling

of the sheet. A highly conformable adhesive wound dressing of this type is known as "OpSite" (Trade mark) marketed by T.J. Smith & Nephew Limited. The "OpSite" wound dressing, which comprises a flexible polyurethane backing, has a pair of plastics strip handles adhered to opposed edges of the adhesive coated sheet to provide non-adhesive surfaces for handling the sheet. After the application of such adhesive wound dressings to a patient the non-adhesive handles are usually removed by cutting from the adhered sheet. Such a method of removal, however, can leave the applied dressing with "lifted" and unevenly cut or ragged edges which can self-adhere or roll up and cause the dressing to progressively "lift off" in use. European Patent Application No. 0081987 and United States Patent No. 4413621 disclose an adhesive wound dressing which comprises a flexible adhesive coated sheet having a pair of non-adhesive handles, formed of the same material as the flexible sheet, adjacent to perforation lines on opposed side edges of the sheet. These handles can be detached from the sheet, after application of the dressing, by separating along the perforation lines. Although the provision of perforations in the sheet allows the handles of such a wound dressing to be removed or detached more easily than the handles of conventional

adhesive wound dressings, the removal of the handles still employs a force which can result in the lifting of the edges of dressing. Furthermore, the edges of the applied dressing, which result from detachment along the perforation lines, are unlikely to be even. Trauma can also be caused to the wound when the edges are pulled during removal of the handles.

United Kingdom Patent Application No. 2120104 describes an adhesive wound dressing and delivery system which comprises a laminate of a semi-rigid non-flexible delivery means layer adhered by a pressure sensitive adhesive to an intermediate wound dressing layer having on the opposite surface to the delivery means a further pressure sensitive adhesive layer covered by a protector. One edge of the wound dressing layer may carry a perforated line and the wound dressing layer in this area may be reinforced by one or more strips. In use after adhering the wound dressing layer at the wound site first the delivery means and then the non-adhesive handle must be removed. The handle is removed along the perforated line which means that the dressing layer is effected by removing the handle which may cause lifting or other disturbance of this layer along its torn edge.

European Patent Application No. 66899 describes a delivery system for an adhesive wound dressing in which a film sheet carrier supports an adhesive coated wound dressing layer. When the dressing is in place the carrier is removed. A non-adhesive tab strip is permanently adhered to one edge of the wound dressing and remains in place after the dressing has been adhered to the patient. The tab forms a non-detachable, non-adherent handle which could lead to the dressing lifting as a result of movement by the patient.

United States Patents Nos. 4372303 and 4374520 each describe a system for bandaging a patient in which a stiff handling means is applied to a flexible, adhesive bandage prior to application of the bandage to a patient. The handling means maintains the bandage in a generally flat configuration during application but because of its stiffness must be removed once the bandage is in place. The removal may cause disturbance to the edge of the applied dressing and may result in the edges self adhering or rolling up so causing the dressing to "lift off" in use.

European Patent Application No. 51935 describes a device in the form of an adhesive dressing comprising a

thin, conformable, adhesive-coated film which has attached to the surface opposite the adhesive layer a supporting releasable layer. After the dressing has been placed on the skin the releasable layer is removed. The removal of the release layer from contact with the applied dressing may cause disturbance of the dressing by lifting its edges.

European Patent Application No. 81989 describes an adhesive dressing comprising an adhesive coated transparent polymeric film and a release sheet covering the adhesive coating. A perforation line is present in the film spaced inwardly from the periphery of the film. A cut line is present in the release sheet spaced inwardly from the periphery of the sheet. In use the central portion of the release sheet is removed by tearing along the cut line, the dressing is adhered to the skin using the remaining release portion as a handling means and finally the remaining release sheet and the periphery of the film are removed by tearing along the perforated line. This will leave an edge to the dressing which is unlikely to be even and which may cause the edge of the dressing to roll up in use.

European Patent Application No. 81990 describes an

adhesive dressing comprising a transparent, continuous, adhesive coated film with a fibrous backing material secured to the side of the film opposite to the adhesive layer. The fabric backing may be removed from the film after the dressing has been placed on the skin of the patient. The force required to remove the fabric backing from contact with the applied dressing may cause disturbance to the dressing.

European Patent Application No. 117632 discloses a surgical dressing in the form of a thin polymeric film having one surface coated with a pressure sensitive adhesive, the adhesive layer is covered with a removable release sheet comprising three sections. In use the centre portion of the release sheet is first removed and the dressing adhesively secured to the patient. The remaining two sections of the release sheet are then removed. This application does not suggest the use of tearable handles.

European Patent Application No. 120570 describes a wound dressing having a protective sheet in releasable contact with the adhesive of an adhesive coated backing sheet. There is a release retarding means along one edge or pair of opposed edges so that a greater force is

required to separate the backing sheet from the protective sheet at the edges than in the central portion of the dressing. In use the central portion of the dressing is exposed and adhered to the patient using the protective sheet which is still joined at its edges to the backing sheet as a manipulation means. When the centre of the dressing is in place the protective sheet is removed by tugging it away from the backing sheet. The force required to remove the parts of the protective sheet may cause the applied dressing to become disturbed.

United States Patent No. 3927669 describes a bandage comprising a hygroscopic pad which has adhered to one surface an adhesive coated strip like element for affixing the bandage to the body. The strip-like element may have a line of perforations whereby the length of the bandage may be shortened by tearing along the perforations. That patent does not disclose or suggest that this would be applicable to membrane dressings of the type envisaged in the present invention.

United States Patent No. 4122552 describes a disposable undergarment having a plurality of bands of strip-away material whereby their selective removal provides garments of varying size. That patent does not

disclose or suggest that this system would be applicable to membrane dressings of the type envisaged in the present invention.

It has now been found that by using a handle which is tearable as an aid to positioning the dressing on a patient, a portion of the handle may be subsequently removed by tearing through the handle without having to tear through the wound dressing layer and so disturb it. Further if the handle is also coated with an adhesive the user has an option of allowing the handle to remain in place by adhering it to the skin or removing part of it and adhering any residual handle to the skin to avoid leaving any loose flaps. A particular advantage of an adhesive handle is that it may be adhered to the patient without having to remove the protector over the adhesive surface of the dressing. The adhered handle may then serve as an anchor point so that both hands are free to manoeuvre the dressing into position and to remove the protector from the dressing prior to adhering it to the skin. This technique of applying the dressing also prevents the dressing being applied under excessive tension. Further the wound dressings of the present invention do not require the presence of an additional delivery means although such may be included if desired.

Accordingly the present invention provides an adhesive wound dressing which comprises a flexible sheet having both an adhesive surface and a non-adhesive surface on the opposite side thereof, a detachable handle at an edge of the sheet to facilitate handling of the sheet and a removable protector over the adhesive surface of the sheet, characterised in that the handle is adhered along an edge margin to an edge margin of the flexible sheet and which handle is formed from a tearable material to allow the handle to be detached from the sheet.

In a preferred aspect the handle will have an adhesive coat on one surface so that it may be adhered to the skin of patient when the dressing is in place. In this aspect the adhesive surface of the handle which is not serving to adhere the handle to the flexible sheet will be covered by a protector prior to use.

From the foregoing it is clear that the adhesive surface on the handle and the adhesive surface on the flexible sheet will be on the same side so that both may be adhered to the body.

Thus in a second aspect the present invention provides an adhesive wound dressing which comprises a

flexible polymer film having both an adhesive surface and a non-adhesive surface on the opposite side thereof, a detachable handle at an edge of the sheet to facilitate handling of the film and a removable protector over the adhesive surface of the film, characterised in that the handle is coated on one surface with an adhesive and is adhered along an edge margin to an edge margin of the flexible film, the remaining area of adhesive of the handle being covered by a removable protector and which handle is formed from a tearable material to allow the handle to be detached from the film.

The adhesive dressings of the present invention are suitable for application to wounds that, is to lesions of the skin, which have been caused either by physical trauma, for example burns, or by surgical intervention, for example post-operative sites, skin donor sites and particularly intravenous sites where a catheter or a cannula has been used to gain access to the venous system of a patient on a long term basis all of which uses require that the site must be protected from infection.

By 'tearable material' is meant material which may be tearable per se or has been adapted to be tearable, for example by edge notching, embossing, orientation or

fibrillation. Generally the tear will be a straight line tear and may be initiated by means of the fingers, thus favourably the material is finger tearable.

The handle used in the wound dressings of the invention can suitably be a film, sheet or web. The handle is preferably stiffer than the flexible adhesive coated film so that it provides support to it during its application to the patient. Suitable handles can be made of a wide variety of materials including paper, non-woven fabric, woven fabric and films, sheets or webs of polymers including polypropylene, polyethylene, copolymers thereof and blends thereof and blends including polystyrene, polyester and polyvinyl chloride. The handle will be either tearable per se like paper or some non-woven and woven fabrics or be adapted to be tearable for example, by edge notching or by embossing or by orienting of a film so as to make it tearable in a preferred direction. Favourably the handle will be adapted to be capable of being torn in a substantially straight line.

Particularly apt materials for forming the handle include paper, porous polyvinyl chloride sheet such as that sometimes known as Porvic (Trade mark) which is conventionally used in the manufacture of first aid

dressings, non-woven fabric such as spun-bonded polyester fabric (Sontara, Trade mark), polyester film (Melinex, Trade mark), woven acrylic fabric, embossed films of low or high density polyethylene or polypropylene, integral nets formed by the fibrillation of embossed films and oriented polypropylene films.

Particularly favoured materials for forming the handle are embossed films particularly those which are melt embossed on one or both surfaces with a series of grooves which delineate the preferred tear direction. Such melt embossed films are described in for example British Patents Nos. 1110051, 1267031, 1495151 and 1496786. Use of such materials gives rise to particularly easily removable handles.

However, particularly preferred materials for forming the handle are integral nets particularly those formed by the fibrillation of thermoplastic embossed polyolefin films comprising low and high density polyethylene, polypropylene or copolymers or blends thereof or blends of polyolefin with polystyrene. Such nets which have been adapted to tear in a preferred direction by orientation of the polymer forming them are described in British Patents Nos 1495151 and 1531715.

A particularly preferred net is formed from a blend of polymers in which a high density medically approved polyethylene forms the major component, for example 5 parts by weight and a high impact polystyrene forms the minor component, for example 1 part. An embossed film of the blend is formed by passing a mixture of the polymers in a molten state through the nip between two rollers, one roller having a pattern of axial grooves on its circumferential surface and the other roller having a pattern of cavities which give rise to raised areas or bosses on one side of the film. Suitably the cavities are hexagonal cavities. The number of grooves per inch may be in the range 50 to 500 and the number of raised areas or bosses 100 to 10. The number of grooves per inch is suitably an integral number of bosses per inch and is 2 to 20 times the number of bosses. The film is then stretched in the transverse direction by at least 50% to fibrillate the areas between the bosses to form a net which is tearable in two directions sustantially at right angles to each other.

An integral net is a net with strands and junctures which have been formed integrally during manufacture.

Since in one method of use the handle may be adhered to the skin rather than being detached, it is preferred that the handle when coated with adhesive should have a moisture vapour permeability (mvp) of at least 300 $gm^{-2}24h^{-1}$ at 37° and 100% to 10% relative humidity when measured by the Payne Cup Method. More suitably the adhesive coated handles should have an mvp of at least 500 $gm^{-2}24h^{-1}$ and preferably should be at least 700 $gm^{-2}24h^{-1}$. The handle may then be safely adhered to the skin without the risk of causing maceration to the underlying normal healthy skin. The method used for measuring moisture vapour permeability is described in European Patent Application No. 107315 at page 52.

An adhesive such as one of those described in British Patent No. 1280631 or European Patent Application No. 35399 may be spread onto the smooth surface of the net as hereinbefore described, that is the one which was embossed with the series of grooves. A particularly suitable adhesive is an acrylate ester copolymer adhesive formed from the polymerisation of 47 parts 2-ethylhexyl acrylate, 47 parts butyl acrylate and 6 parts acrylic acid. This combination of net and adhesive gives a tape of both high

moisture vapour permeability (mvp) and tearability which is particularly apt for the dressings of the present invention. If the adhesive layer is continuous the mvp is approximately 800 $gm^{-2}24hr^{-1}$ and if the adhesive layer is porous the mvp may be as high as 8000 $gm^{-2}24hr^{-1}$, when measured at 37°C and 100% to 10% relative humidity.

Suitably the handle will be from 1.0 cm to 4.0 cm in width and preferably 1.5 to 2.5 cm in width, for example 1.8 cm, 2.0 cm or 2.2 cm in width. The width of the margin of the handle which is adhered to the edge margin of the flexible sheet is then suitably 0.15 to 0.5 cm and is preferably 0.2 to 0.3 cm.

In another favoured embodiment the handle is formed from a plastics film handle portion and an adhesive tape. The handle portion may or may not have an adhesive layer on one surface thereof. The handle portion is positioned abutting the flexible film. The adhesive tape is placed over an edge margin of the flexible film and at least an edge margin of the handle portion so as to attach the flexible film and the handle portion. A line of perforations is present through the adhesive tape. The line of perforations is positioned over the joint between the flexible film and the handle portion so that neither

the flexible film nor handle portion is perforated, but separation of the handle is achieved by tearing along the perforated line. The adhesive tape may be formed from a paper coated on one surface with a pressure sensitive adhesive. Both the adhesive tape and handle portion may also be coloured for example green. If it is required to adhesive coat the handle portion, the adhesive surface will be covered by a release coat.

In an alternative construction the handle portion may be offset from the flexible film so that a wider tape is required to attach the handle portion to the flexible film. The exposed adhesive surface of the tape is covered by the protector which also covers the adhesive surface of the flexible film. The line of perforations is so positioned so as to allow the residual adhesive tape on the flexible film to be adhered to the skin after removal of the handle thereby providing a neat edge to the dressing.

In one embodiment of the invention the adhesive wound dressings will have only one handle. Such dressings are conventionally preferred for use at intravenous sites.

In a second embodiment of the invention the adhesive wound dressing will have a handle at each of two opposite

sides of the wound dressing. Such dressings are conventionally preferred for use on wounds caused by physical trauma or surgical invention though they may equally well be used in conjunction with indwelling catheters or cannulae.

The flexible polymer film which have both an adhesive coated surface and a non-adhesive coated surface on the opposite side of the film may comprise any of the flexible polymer films conventionally used for surgical or wound dressings. The sheet material is a polymer film and most preferably a film of elastomer. Preferably the flexible film is moisture vapour permeable and bacteria proof. In addition it is most convenient to employ a transparent material. Favoured moisture vapour permeable, liquid water impermeable, flexible sheets will have a moisture vapour permeability of at least 300 $gm^{-2}24h^{-1}$ at 37°C at a relative humidity difference of 100% to 10%, more suitably at least 400 $gm^{-2}24h^{-1}$, preferably at least 500 gm^{-2} $24h^{-1}$ and most preferably at least 700 $gm^{-2}24hr^{-1}$.

Suitable flexible films for use in the invention are described in British Patent No. 1280631 and European Patent Application No. 51935. Favoured flexible polymeric

films include those formed from a polyether or polyester polyurethane. Suitable polyether polyurethanes are described in United States Patent No. 2899411, and suitable polyester polyurethanes are described in United States Patent No. 2871218. Suitable polyether and polyester polyurethanes include those known as Estanes (Trade mark, available from B.F. Goodrich Corp.). Preferred polyurethanes are available as Estanes 5701, 5702, 5703, 5714F and 580201. A second particularly favoured flexible film may be formed from an elastomeric polyether polyester. Preferred polyether polyesters include Hytrel 4056 (Trade mark, available from E.I. du Pont de Nemours & Co.).

Suitably the thickness of the flexible films used in the invention will be from 9 to 80 microns, more suitably 15 to 50 microns and preferably 20 to 40 microns for example 25 microns, 30 microns or 35 microns.

A second favoured form of adhesive wound dressing to which tearable handles may be applied is described in European Patent Application No. 107915.

That application describes a moisture vapour permeable adhesive surgical dressing comprising a continuous film

which has a moisture vapour permeability which is greater when in contact with water than when not in contact with water and which film is attached to a water transmitting film so as to form a sealed portion into which exudate may pass from an exuding wound, said water transmitting layer being interrupted in at least the area within the sealed portion and which water transmitting layer comprises a backing layer and an adhesive layer on the side remote from the continuous film which is suitable for adhering the dressing to the skin. Such a dressing is suitable for attachment of handles formed from tearable material as hereinbefore described. Aptly a margin at the edge of the handle will be attached to a margin of the continuous moisture vapour permeable sheet. Attachment may be by any conventional means but use of an adhesive is preferred. The handle is aptly attached on the surface remote from that sealed to the water transmitting film though if desired the handle could be attached so that its margin was sealed between the moisture vapour permeable film and the water transmitting film.

A particularly preferred adhesive wound dressing has a continuous film formed from a hydrophilic polyurethane, a water transmitting film formed from an adhesive coated low moisture vapour permeable polymer film, such as a

styrene-butadiene-styrene polymer, which has been apertured by means of a plurality of slits and in which a layer of a water transmitting film of a non-woven fabric, such as a spun-bonded polypropylene is present between the continuous film and the water transmitting film.

When present the adhesive layer on the handle used in dressings of the present invention may be a continuous spread or a non-continuous spread, for example pattern spread, a microporous layer or a porous layer.

Suitably the adhesive layer will be 15 to 65 microns thick, preferably is 20 to 40 microns thick, for example 25, 30 or 35 microns thick. Such adhesive layers will generally have a weight of adhesive per unit area of 10 to 75 gm^{-2}, more usually 15 to 65 gm^{-2} and preferably 26 to 40 gm^{-2}.

Suitable adhesives include those which are described in British Patent No. 1280631 and European Patent Applications Nos. 51935, 35399. Preferably, the adhesive is a polyvinyl ether adhesive such as polyvinyl ethyl ether adhesive or an acrylate adhesive such as an acrylic ester adhesive. Examples of the latter include acrylate ester copolymers which contain hydrophilic groups, for example a copolymer of 47 parts by weight butyl acrylate,

47 parts by weight 2-ethylhexyl acrylate and 6 parts by weight acrylic acid.

If the adhesive layer is a continuous spread then it is prepared from a material which when spread on a handle or flexible sheet will allow the adhesive coated material to have a moisture vapour permeability (mvp) of at least 300 $gm^{-2}24h^{-1}$ at 37°C and 100% to 10% relative humidity when measured by the Payne Cup Method, more favourably the mvp will be at least 400 $gm^{-2}24h^{-1}$, most favourably at least 500 $gm^{-2}24h^{-1}$ and preferably at least 700 $gm^{-2}24h^{-1}$.

A similar adhesive may be used on the flexible polymer film present in the wound dressings of this invention and will be applied in a similar continuous or discontinuous manner and suitably will give the moisture vapour permeabilities hereinbefore described.

Since the adhesive wound dressings of the present invention are to be adhered to normal healthy skin then to avoid maceration of that skin then it is arranged that the adhesive wound dressing will have a moisture vapour permeability of at least 300 $gm^{-2}24h^{-1}$ at 37°C and 100% to 10% relative humidity, more suitably will be at least 500 $gm^{-2}24h^{-1}$ and preferably will be at least

700 $gm^{-2}24h^{-1}$.

In the dressings of the present invention, the handle and the flexible sheet overlap at their edge margins. Irrespective of whether the rest of the handle is removed or adhered to the skin this overlap area will remain on the dressing and will by virtue of the adhesive on the flexible sheet be adhered to the skin. In order to avoid maceration of the underlying skin in this overlap area, the dressing in this area will favourably have an MVP oof at least $300gm^{-2}24hr^{-1}$ at 37°C and 100% to 10% relative humidity difference, more favourably the MVP will be at least $500gm^{-2}24hr^{-1}$ and preferably be at least $700gm^{-2}24hr^{-1}$.

Suitable protectors include silicone release coated papers and plastics coated papers and release coated films such as silicone coated polyethylene. A favoured release protector is a silicone release/polyethylene coated paper known as Steralease No. 15 (Trade mark, available from Sterling Coated Paper Limited).

The adhesive wound dressing of the invention will usually have a rectangular shape. Suitable wound dressings have a size of 8cm x 8cm to 20cm x 20cm for example 10cm x 10cm, 10cm x 15cm, 15cm x 15cm, etc.

The adhesive wound dressing of the invention is preferably sterile. The adhesive wound dressing of the invention is advantageously provided within a bacteria proof pack such as a sealed aluminium foil or paper/plastics film pouch. Sterilization of the dressing can be carried out by a conventional sterilizing method such as ethylene oxide, electron or gamma radiation.

In another aspect the invention provides a process of making an adhesive wound dressing of the invention which comprises attaching the edge margin of a handle to an edge margin of a flexible adhesive coated film which handle is formed from a tearable material whereby a portion of the handle may be detached from the film.

Suitable adhesive coated films and handles for use in the process of the invention are described hereinbefore in relation to the adhesive wound dressing of the invention.

The flexible film may be formed by casting or extrusion onto a support film, usually the non-release surface of a conventional release paper or polymer. The adhesive layer may be formed by casting or transfer coating onto the surface of the flexible film. The adhesive surface of the flexible film may then be

transferred onto the release surface of the support film. The three layer laminate is then cut into a strip having the width of the required dressing.

The handles when adhesive may be formed by transfer coating an adhesive layer on a release paper onto the material forming the handle. This may then be cut into a strip of the appropriate width and attached to the edge of the flexible film.

The process of the invention may be carried out as a continuous process using continuous lengths of the flexible adhesive film and handles. Dressings of suitable size can then be made by cutting across the formed strips. In a process for making wound dressings which have a pair of handles at opposed side edges, the handles may be attached in consecutive or preferably simultaneous operation.

The preferred embodiments of the dressings of the invention will be described by way of example and with reference to the drawings in which:

Figure 1 is a plan view of an adhesive wound dressing of the invention.

Figure 2 is a cross-sectional view of the dressing

along line A-A of Figure 1.

Figure 3 is a cross-sectional view of an alternative embodiment of the present invention.

Figure 4 is a cross-sectional view of an adhesive wound dressing which has only one handle.

Figure 5 is a cross-sectional view of an adhesive wound dressing in which the handles do not carry an adhesive.

Figures 6 to 9 show cross-sections through alternate embodiments of adhesive wound dressings of the present invention.

Figures 10 to 12 show cross-sections through alternate embodiments of adhesive wound dressings of the present invention in which tearable handles are used in combination with dressings described in European Patent Application No. 107315.

Figures 1 and 2 show an adhesive wound dressing (1) which is of rectangular shape. The dressing comprises a flexible adhesive coated film (2) consisting of a flexible backing film (3) and an adhesive coating (4) which is covered by a protector (5). The adhesive wound dressing

(1) has a pair of handles (6) at opposed side edge margins (7) of the flexible film (2). The handles (6) are coated with a layer of adhesive (8) so that the edge margins (9) of the handles (6) are attached to the edge margins (7) of the film (2) by means of a portion of this adhesive coating (8). The remainder of the adhesive surfaces on the handles (6) are covered with removable protectors (10). The protector (5) which covers the adhesive coating (4) may be extended to provide strips (11) which aid in removal of the protector from the adhesive wound dressing, by adhering the strips (11) using tabs (12).

Figure 3 shows an alternative adhesive wound dressing in which the protector (5) is formed of one piece which extends beyond the edges of the adhesive coated film (2) so that the extending pieces provide an aid to removal of the protector.

Figure 4 shows an adhesive wound dressing in which only one adhesive handle is present. Such dressings are used at intravenous sites.

Figure 5 shows an adhesive wound dressing in which the handles are essentially non-adherent, being coated with adhesive only at their margins (9) where they are adhered to the margin of the flexible film.

Figure 6 shows a further embodiment of an adhesive dressing of present invention in which the adhesive wound dressing (1) is formed from the conventional three layers comprising a flexible film (3) having on one surface a pressure sensitive adhesive layer (4) and a protector (5). One edge of the dressing has a handle (6) coated with a layer of adhesive (8) so that the edge margin (9) of the handle (6) can be attached to the edge margin (7) of the film (2). The remainder of the adhesive layer (8) is covered with a removable protector (10). At this edge, the protector (5) may be extended to provide a strip (11) which aids in the removal of the protector (5) from the adhesive wound dressing (1). The extra strip (11) is adhered to the protector (5) using adhesive-coated tab strip (12). The other edge of the dressing has adhered to its margin (13), an adhesive coated handle of a tearable material (14, 15). The protector (16) which covers the adhesive surface (15) of the handle (14) overlaps into the non-adhesive surfaceof the flexible film (3). In use the protector (16) is removed from the handle and the adhesive surface of the handle adhered to the patient to form an anchorage point for the dressing. The dressing is then positioned over the wound site and the protector (5) removed. The other handle is used to prevent both

contamination of the exposed adhesive surface of the dressing and to prevent the dressing from wrinkling during the application process. When the dressing has been adhered to the skin, then the remaining handle may be removed or adhered to the patient.

Figure 7 shows an embodiment of the adhesive dressing of the present invention similar to that described in Figure 6 except that the protector (16) overlaps onto protector (5) of the wound dressing layer. In this embodiment the handle (14) is adhered to the skin of the patient prior to removal of the protector (5).

Figure 8 shows a further embodiment of an adhesive wound dressing of the present invention which comprises a flexible adhesive sheet (22) which comprises a flexible film (23) having on one surface thereof an adhesive layer (24) which adhesive layer is covered by a protector (25) which extends beyond the edges of the flexible adhesive film on at least two opposite edges. A handle (26) comprising a handle portion (27) and an adhesive tape (28) is shown on two opposite edges of the flexible film. The handle comprises a non-adhesive carrying handle portion (27) which is placed abutting the flexible film and an adhesive tape (28) which is used to attach the

non-adhesive handle portion to the flexible film. Both the handle portion and the adhesive tape may be coloured in a distinctive colour for example green. The adhesive tape carries a line of perforations (29) which extend over the length of the handle and enable the handle to be separated from the adhesive flexible film without disturbing the flexible film.

Figure 9 shows an alternative embodiment to that shown in Figure 8 in that instead of abutting the flexible film, the handle portion is placed a distance from the edge of the flexible film. The perforation line (29) is likewise placed away from the edge of the flexible film so that that when the handle portion is removed along the perforation line a short width of adhesive coated handle remains and may be adhered to the skin of the patient. Again the handle is removed without disturbing the flexible film wound dressing.

Figure 10 shows an adhesive wound dressing (31) which comprises a layer of hydrophilic polyurethane (32) sealed around its edges to a film of styrene-butadiene-styrene polymer (33) which has been made water transmitting by cutting slits through it. On one surface this apertured film has an adhesive layer (34) covered by a protector

(35) which has been extended by strips (36) attached by means of adhesive coated tabs (37). The tearable handles comprise adhesive coated (38) fibrillated film (39). The edge margin (40) of the handles is adhered to the edge margin of the hydrophilic polyurethane film (41). The remainder of the adhesive on the handles is covered by a protector (42).

Figure 11 shows an adhesive wound dressing in which the handles comprise a non-adhesive coated handle portion (43) which is placed abutting the hydrophilic polyurethane film and is attached to it by means of an adhesive coated tape (44). The tape has a line of perforations (45) positioned above the joint of the handle portion and the hydrophilic polyurethane film so that the handle may be removed by tearing along the perforated line without disturbing the wound dressing.

Figure 12 shows an adhesive wound dressing in which the handles (46) are non-adhesive and are attached to the dressing by means of the adhesive on the water transmitting film.

The adhesive wound dressings shown in the drawings can be applied to a patient by holding the adhesive sheet by means of the handles, removing the protector from the

adhesive coating and adhering the adhesive sheet over the wound site. The handles may then be left or torn from the edges of the dressing or when the handles are adhesive coated the protector may be removed from the adhesive layer and the handles adhered to the skin of the patient, in each case to provide a dressing which is completely adhered to the patient without non-adhesive or ragged edges.

In a further aspect the invention provides a method for treating a wound using the adhesive wound dressing of the invention which comprises removing the protector from the adhesive coating, adhering the flexible adhesive coated sheet to the skin surrounding the wound and removing a portion of the handle by tearing along the length of the handle without tearing through the adhesive coated sheet material.

In a second further aspect the invention provides a method for treating a wound using the adhesive wound dressing of the invention which comprises removing the protector from the adhesive coating, adhering the flexible adhesive coated sheet to the skin surrounding the wound, removing the protector from the adhesive coated handle and adhering to the handle, to the skin.

Alternatively the adhesive wound dressings which have adhesive handles can be applied to a patient by first removing the protector strip from one of the handles and adhering it in the required position on the skin to form an anchor point for the dressing. The protector is then removed from the adhesive surface of the wound dressing layer and using the other handle, it can be manoeuvred into its required position. When the dressing is adhered to the skin the remaining handle may be adhered to the skin or torn off. The handle which provided the anchor point may similarly be left in position or removed by tearing. The dressing when applied is not subject to tension found when applying prior art dressings and is therefore more comfortable and does not buckle or crease when the tension is released as the patient moves.

In a further aspect therefore the invention provides a method for treating a wound using the adhesive wound dressing of the invention which comprises removing the protector from one of the adhesive coated handles and adhering it to the skin, peeling off the protector from the adhesive coating of the wound dressing adhering flexible, adhesive coated sheet to the skin surrounding the wound removing the protector from the second handle

and adhering it to the skin.

EXAMPLE 1

Preparation of Adhesive Wound Dressing with Adhesive Handles

(a) A flexible elastomeric film of polyurethane was formed by dissolving a polyether polyurethane (Estane 5714F, Trade mark, available from B.F. Goodrich Co.) in tetra hydrofuran at 20% solids and casting onto the non-siliconised side of a silicone coated release paper (Steralease 15, Trade mark). Removal of the solvent gave a film which was 30 microns thick. This film was in turn coated with a layer of a polyvinyl ethyl ether pressure sensitive adhesive (adhesive composition A of British Patent No. 1280631). The adhesive layer was 30 microns thick. The polyurethane and adhesive were then transferred to the other side of the release paper in a conventional manner and the three layers slit to give a strip 10cm wide, which is a suitable size for a wound dressing. The adhesive layer now in contact with the siliconised surface of the release paper.

(b) A siliconised release paper was coated on its silicone coated side with polyvinyl ethyl ether adhesive to give a film which was 30 microns thick. When the film

of adhesive had been formed and the solvent removed the adhesive was laminated to a fibrillated thermoplastic film material formed by the method described in British Patent No. 1531715. This laminate which forms the handles of the adhesive dressing was slit to give a strip 2.0cm wide.

(c) A siliconised release paper was coated on its non-siliconised side with a polyvinyl ethyl ether adhesive and cut into a strip 1cm wide.

(d) A siliconised release paper was slit to give a strip 2cm wide.

The adhesive wound dressing shown in Figure 2 was then assembled as follows: the release paper of (d) is placed adjacent to the release paper of the laminate formed in (a) and the strip of tape formed in (c) used to join the two release papers together. This provides the handles for the protector.

The release paper of the laminate formed in (b) is placed adjacent to the polyurethane film of the laminate formed in (a) and the adhesive coated fibrillated film material formed in (b) moved sideways so that the adhesive edge margin of the fibrillated film material is attached to the edge margin of the polyurethane film. The

remainder of the adhesive surface of the fibrillated film material is covered by the release paper. A similar handle portion may be attached in a similar manner to the opposite edge of the polyurethane film.

The strip so formed may be cut across its width to provide a wound dressing which may then be placed in a conventional bacteria proof package, sealed and sterilised either by ethylene oxide or gamma irradiation.

In use the dressing is removed from its package, the protector peeled off and the handles used to position the dressing at the appropriate site. The handles may then be detached, left with the protector in place or the protector removed from the handles and the handles adhered to the skin.

EXAMPLE 2

A dressing was prepared in a similar manner to that described in Example 1 except that only one handle was placed at the edge of the adhesive coated polyurethane film.

This dressing is particularly useful as a dressing for intravenous sites.

EXAMPLE 3

An adhesive coated flexible sheet in which the adhesive surface is covered by a protector is formed in a similar manner to that described in (a) of Example 1.

A siliconised release paper is coated as a strip approximately 0.25cm wide with a polyvinyl ethyl ether adhesive, to give a film approximately 30 micron thick. This strip is then transfer coated to an edge margin of fibrillated thermoplastic film material formed by the process described in British Patent No. 1531715. The adhesive strip is then used to adhere the handle material to the edge margin of non-adhesive surface the flexible sheet.

The resultant strip may be cut across its width to provide rectangular dressings.

The dressings may be placed in bacteria proof pouches sealed and sterilised by gamma irradiation or ethylene oxide.

EXAMPLE 4

A dressing was prepared by a similar method to that described in Example 1 except that the fibrillated

thermoplastic film was replaced by a melt embossed film which had been embossed by means of grooves on each surface of the film which provided a preferred direction of tear which enabled the handles to be removed.

This dressing was packed and sterilised in a conventional manner.

EXAMPLE 5

A dressing was prepared by a similar method to that described in Example 1 except that the handles were formed from a paper which was finger tearable.

EXAMPLE 6

A dressing was prepared by a similar method to that described in Example 1 except that the handles were formed from a 150 micron thick film of polyvinyl chloride which was microporous (Porvic, Trade mark). The adhesive used to coat the handles was in the form of a pattern spread formed by the method described in British Patent No. 815635.

This dressing may be packed and sterilised in a conventional manner.

EXAMPLE 7

A dressing was formed by a similar manner to that described in Example 1 except that the handles were formed from a spun bonded polyester non-woven fabric (Sontara, Trade mark available from Du Pont de Nemours).

EXAMPLE 8

A dressing was formed by a similar method to that described in Example 1 except that the flexible backing sheet was formed from a 32 micron thick film of an elastomer polyether polyester, Hytrel 4056.

The dressing was packed in a bacteria proof pack and sterilised in by gamma irradiation or by ethylene oxide.

EXAMPLE 9

An adhesive coated flexible sheet in which the adhesive surface is covered by a protector is formed in a similar manner to that described in (a) of Example 1 except that the protector extends beyond the edges of the adhesive flexible sheet which are to be attached to the handles.

A film of polyester (Melinex, Trade mark), to form the handle portion, is laid on the protector extension and abuts the flexible sheet. A strip of perforated, adhesive coated sheet is then placed on top of the margin of the flexible sheet and of the polyester film handle portion so that the perforated line lies above the gap between the sheet and the film. The strip thus attaches the sheet and the polyester film and with the polyester film forms a handle which is removable by tearing along the perforations so that neither the flexible sheet nor the polyester film is disturbed.

The dressings when cut to the correct size may be placed in bacteria proof pouches, sealed and sterilised.

In use a dressing is removed from its pouch, the protector removed from the adhesive surface of the flexible sheet and the non-adhesive handle portion used to position and place the dressing at the correct site. The handles may then be removed by tearing along the perforated line, so that neither the flexible sheet nor the handle portion is actually torn through.

EXAMPLE 10

(a) An adhesive coated flexible sheet in which the adhesive surface is covered by a protector was formed in a similar manner to that described in (a) of Example 1.

(b) A siliconised release paper was coated on its silicone-coated surface with a polyvinyl ethyl ether adhesive to give a film which was 30 microns thick. When the film of adhesive had been formed and the solvent removed the adhesive was laminated to a fibrillated thermoplastic film material formed by the process described on British Patent No. 1531715. This laminate was slit to give a strip 4.0cm wide.

(c) A siliconised release paper was coated on its non-siliconised side with a polyvinyl ethyl ether adhesive and cut into a strip 1cm wide.

(d) A siliconised release paper was slit to give a strip 2cm wide.

To prepare the dressing the release paper of (d) is placed adjacent to the release paper of the laminate formed in (a) and the strip of tape formed in (c) used to join the two release papers together. This is done on just one edge of the laminate of (a) and forms a handle

for the protector.

At the same edge of the laminate of (a),the release paper of the laminate formed in (b) is placed adjacent to the polyurethane film and the adhesive coated fibrillated film material of (b) moved sideways so that the adhesive edge margin of the fibrillated film material is attached to the edge margin of the polyurethane film. The remainder of the adhesive surface of the fibrillated film material is thus covered by the release paper. On the opposite edge of the laminate of (a) a handle was not added to the protector. The adhesive coated fibrillated film material was moved sideways as previously. The protector which covered the adhesive coated fibrillated film material was also moved sideways so as to overlap onto the protector covering the flexible sheet material. The remainder of this protector covers the adhesive surface of the fibrillated film.

The strip so formed may be cut across its width to provide a wound dressing which may then be placed in a conventional bacteria proof package, sealed and sterilised.

In use the dressing is removed from its package, the protector which covers the adhesive on the handle and

overlaps onto the protector of the flexible adhesive sheet is removed and the handle adhered in the required position on the skin. Using this as an anchor point, the protector is removed from the flexible adhesive sheet using the protector handle at the opposite edge and the dressing is then adhered to the skin using the remaining handle to provide support during this operation. In this way the dressing is applied without use of excessive tension and avoids the risk of contamination by aseptic contact of the exposed adhesive surface with a person applying the dressing. The handle may be removed by tearing or may be adhered to the skin.

EXAMPLE 11

An adhesive dressing was formed by the method described in Example 5 of European Patent Application No. 107915 in which the continuous layer was formed from a hydrophilic polyurethane which would contain 25% by weight of water, and the water transmitting film comprised a styrene-butadiene- styrene block copolymer (Kraton 1101, Trade mark) with an adhesive coating of an acrylic ester copolymer described in European Patent Application No. 39599 covered by a silicone release paper. The Kraton film, adhesive and protector were apertured by means of a

plurality of slits.

A tearable handle was prepared and attached to the surface of the hydrophilic polyurethane remote from the water transmitting film in a similar manner to that described in Example 10.

The dressing may be sealed in a bacteria proof pouch and sterilised in the usual way.

EXAMPLE 12

A dressing was formed in a similar manner to that described in Example 11 except that a layer of a non-woven fabric in the form of a spun-bonded polypropylene (Novelin, Trade mark) was present between the hydrophilic polyurethane and the Kraton film layers.

CLAIMS

1. An adhesive wound dressing which comprises a flexible polymer film having an adhesive surface and a non-adhesive surface on the opposite side thereof, a detachable handle at an edge of the film to facilitate handling of the film and a removable protector over the adhesive surface of the film characterised in that the handle is adhered along an edge margin of the flexible film and which handle is formed from a tearable material to allow a portion of the handle to be detached from the film.

2. An adhesive wound dressing which comprises a flexible polymer film having an adhesive surface and a non-adhesive surface on the opposite side thereof, a detachable handle at an edge of the film to facilitate handling of the film and a removable protector over the adhesive surface of the film, characterised in that the handle is coated on one surface with an adhesive and is adhered along an edge margin to an edge margin of the flexible film, the remaining area of adhesive of the handle being covered by a removable protector and which handle is formed from a tearable material to allow a portion of the handle to be detached from the film.

3. An adhesive dressing as claimed in either of claims 1 or 2 in which there is a handle at each of two opposite sides of the flexible film which film is an elastomeric polymer.

4. An adhesive dressing as claimed in any of claims 1 to 3 in which the flexible film is a moisture vapour permeable polyurethane film which has a thickness of 10 to 50 microns.

5. An adhesive dressing as claimed in any of claims 1 to 4 in which the handle comprises an integral net formed by the fibrillation of a thermoplastic, embossed film.

6. An adhesive dressing as claimed in claim 2 in which the adhesive coated handle has a moisture vapour permeability of at least $300gm^{-2}24h^{-1}$ at $37^{o}C$ and 100% to 10% relative humidity difference whereby the handle may be adhered to the skin.

7. An adhesive dressing as claimed in claim 2 in which the adhesive coating on the handle is an acrylic ester copolymer pressure sensitive adhesive.

8. An adhesive dressing as claimed in any of claims 1 to 7 in which the composite strip formed by adhering the edge margin of the handle to the edge margin of the flexible film has a moisture vapour permeability of at least $300gm^{-2}24h^{-1}$ at 37°C and 100% to 10% relative humidity difference.

9. An adhesive dressing as claimed in either of claims 1 or 2 in which the handle comprises a handle portion and an adhesive tape having a line of perforations along its length whereby the adhesive tape is placed over an edge portion of the flexible film and at least an edge portion of the handle portion with the line of perforations over the joint between the flexible film and the handle portion so that by tearing along the perforations the handle portion may be detached from the flexible film.

10. An adhesive dressing as claimed in either of claims 1 or 2 in which the handle is from 1.0 to 4.0cm in width.

11. An adhesive wound dressing comprising a continuous film which has a moisture vapour permeability which is greater when in contact with water than when not in contact with water and which film is attached to a water

transmitting film so as to form a sealed portion into which exudate may pass from an exuding wound, said water transmitting layer being interrupted in at least the area within the sealed portion and which water transmitting layer comprises a backing layer and an adhesive layer on the side remote from the continuous film which is suitable for adhering the dressing to the skin, a removable protector over the adhesive layer of the water transmitting layer characterised in that a detachable handle is adhered along an edge margin to an edge margin of the continuous moisture vapour permeable film and which handle is formed from a tearable material to allow a portion of the handle to be detached from the film.

12. An adhesive dressing as claimed in claim 11 in which the handle has an adhesive coating.

13. An adhesive dressing as claimed in either of claims 11 or 12 in which there are two handles adhered to opposite sides of the dressing.

14. An adhesive dressing as claimed in any of claims 1 to 13 in which the dressing is sterile and is packaged in a bacteria proof pack.

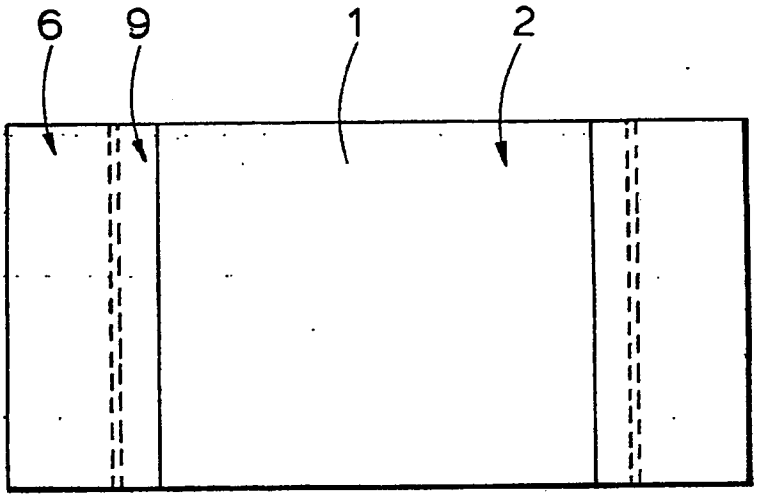

Fig.1

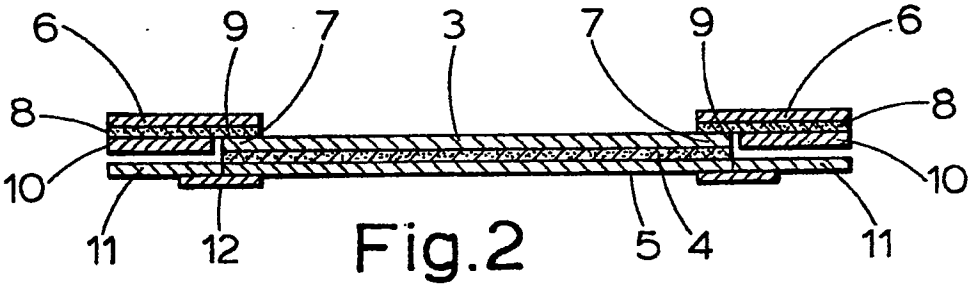

Fig.2

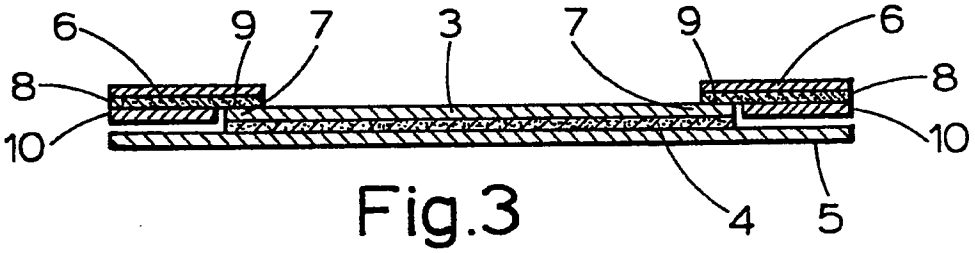

Fig.3

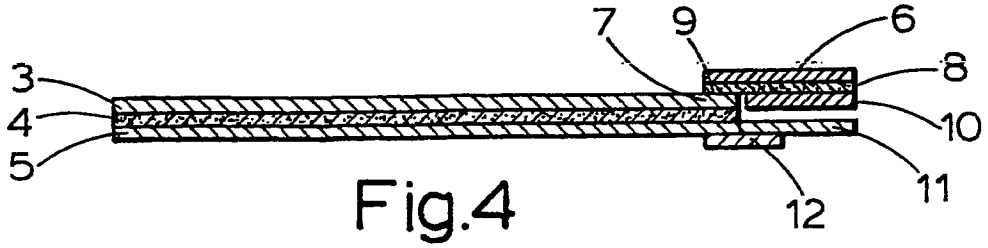

Fig.4

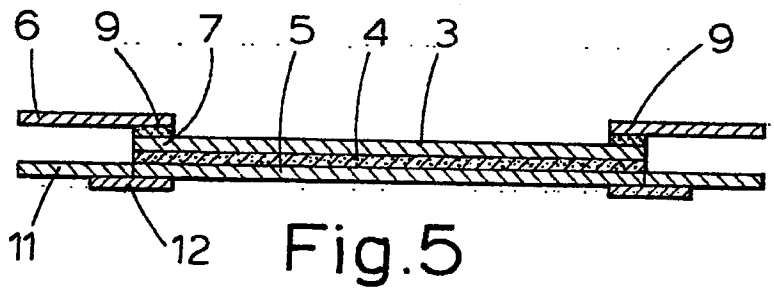

Fig.5

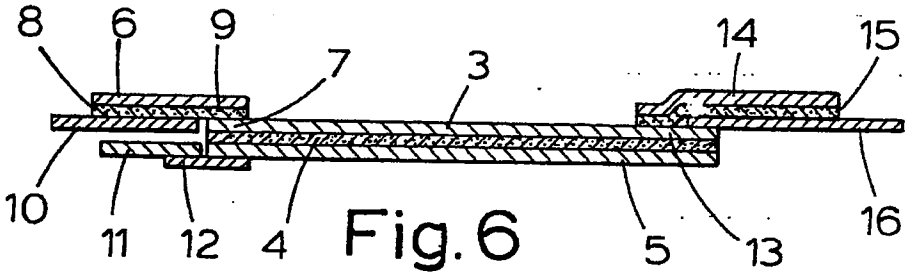

Fig.6

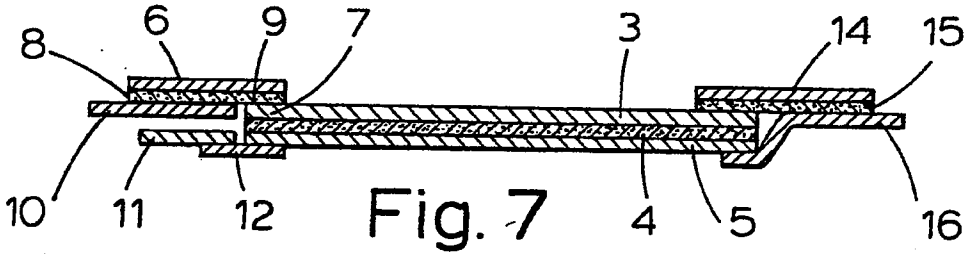

Fig. 7

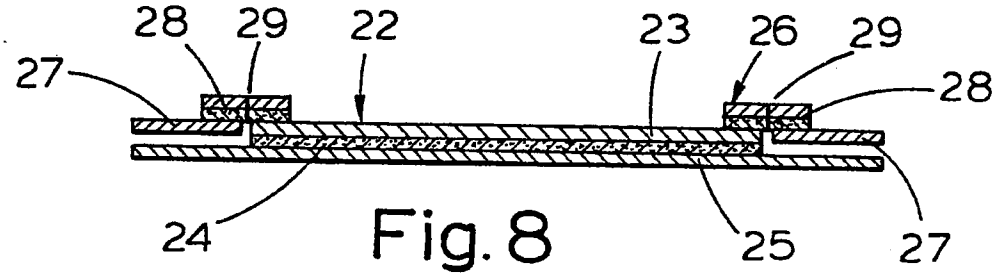

Fig. 8

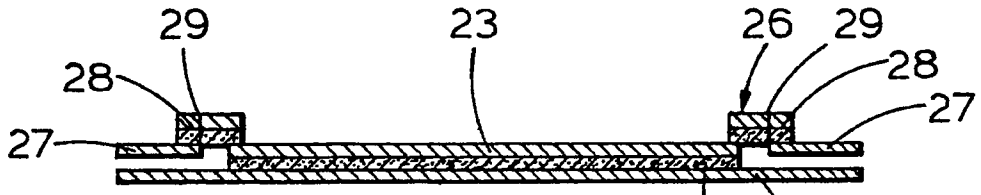

Fig.9

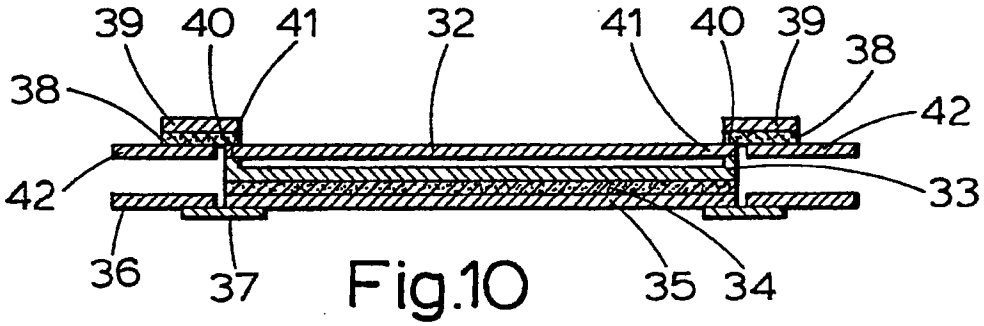

Fig.10

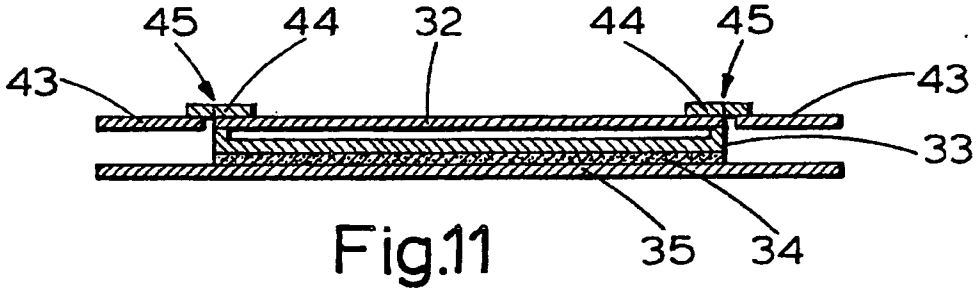

Fig.11

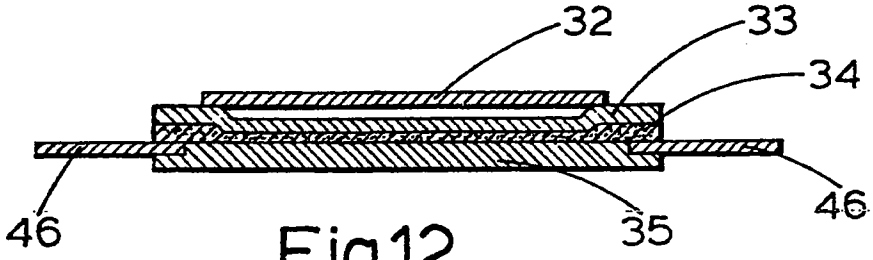

Fig.12

(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) Publication number: 0 358 302 A2

(12) EUROPEAN PATENT APPLICATION

(21) Application number: 89305170.6

(51) Int. Cl.5: A61M 1/00

(22) Date of filing: 23.05.89

The title of the invention has been amended (Guidelines for Examination in the EPO, A-III, 7.3).

(30) Priority: 28.05.88 GB 8812803

(43) Date of publication of application: 14.03.90 Bulletin 90/11

(84) Designated Contracting States: AT BE CH DE ES FR GR IT LI LU NL SE

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(54) Medico-surgical suction container.

(57) A medico-surgical suction container has an inlet 10 connected to a suction catheter 11 and an outlet 20 connected to a pump 21 capable of reducing pressure in the container to at least 500 mm Hg below atmosphere. Within the container, in line with the outlet 20, is a housing 44 containing a filter 41 having a layer of a PTFE membrane on a support screen and a layer of a glass microfibre laminated to a polymer monofilament. The filter 41 allows passage of gas from the container but prevents passage of bacteria and liquid. A tube 43 projects down from the filter housing 44 into the container, the lower end of which defines the maximum filling level, thereby preventing overfilling of the container. The inlet 10 and outlet 20 are formed in recesses 13 and 23 which can be sealed by plugs 14 and 24 attached to the container by flexible webs 15 and 25. The plugs 14 and 24, when inserted, form a smooth surface of the recesses, thereby preventing subsequent removal. An expansion chamber 30 has a convex base plate 31 beneath the inlet 10 so that liquid flows outwardly and down the edge of the plate between a gap 32 with the container and through slots 33 at the edge of the plate.

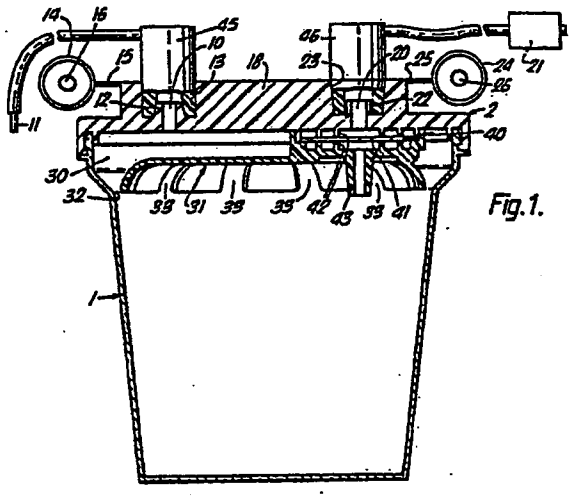

Fig.1.

EP 0 358 302 A2

MEDICO-SURGICAL CONTAINERS

This invention relates to medico-surgical containers of the kind having an inlet for connection to a suction catheter and an outlet for connection to a vacuum pump.

The invention is more particularly concerned with containers for collecting liquid and other debris removed from a surgical site by suction in a suction system.

Suction applied by a vacuum pump is used to remove blood, irrigation liquid, tissue debris and the like during surgery. The suction system commonly comprises a suction catheter, a vacuum pump and a collection container. The collection container has two openings one of which is connected to the suction catheter and the other of which is connected to the vacuum pump. The reduced pressure produced by the vacuum pump is communicated with the suction catheter via the container so that material in the surgical site can be sucked along the catheter and collected in the container.

Such collection containers usually have a float-actuated ball valve in the outlet connected to the vacuum pump, the ball valve closing when the liquid in the container rises above a preset level, so as to prevent the liquid being sucked into the vacuum pump. A bacterial filter is often connected between the container and the pump to prevent any airborne or aerosol-borne bacteria being dispersed to the atmosphere.

Because the contents of the collection container after use are often contaminated, their safe disposal presents problems.

It is an object of the present invention to provide an improved medico-surgical container.

According to the present invention there is provided a medico-surgical container of the above-specified kind, characterised in that the container includes a filter located in the container in line with the outlet and that the filter allows passage of gas from the container to the outlet but prevents passage of bacteria and liquid such that overfilling of the container is prevented by the filter.

In this way, the need for a separate float valve and bacterial filter is obviated.

The filter is preferably contained within a housing having a tube projecting downwardly into the container, the lower end of the tube defining the maximum filling level of the container. The filter may include a layer comprising a PTFE membrane on a support screen and may include a layer including a glass microfibre laminated to a polymer monofilament.

The inlet and outlet may be located in recesses, the container including plugs shaped for insertion in the recesses to seal off the inlet and outlet and to form a smooth surface of the recess making subsequent removal of the plug difficult. The plugs may be each attached to the container by means of a flexible web.

The container preferably includes an expansion chamber beneath the inlet. The expansion chamber may have a base plate of convex shape located such that the liquid from the inlet flows outwardly and down the edge of the plate. The outlet from the expansion chamber is preferably at the edge of the base plate and may include slots formed at the edge of the base plate.

A suction system including a suction container in accordance with the present invention will now be described, by way of example, with referene to the accompanying drawings.

Figure 1 is a sectional side elevation view of the container;

Figure 2 is a perspective view of the top of the container;

Figure 3 is a perspective view of the interior of the top of the container; and

Figure 4 is a sectional elevation through the filter member of the container.

With reference first to Figures 1 and 2, the surgical suction system includes a container comprising a cylindrical, transparent jar 1 of a plastics or glass and a top closure 2 that is irremovably sealed to the jar. An inlet 10 and outlet 20 are provided in the top closure 2 that are connected respectively to a suction catheter 11 and a vacuum pump 21 capable of delivering a vacuum of at least 500 mm Hg below atmosphere in the jar 1.

The inlet 10 and outlet 20 both have a vertical spigot 12 and 22 located within respective cylindrical recesses 13 and 23 formed in a handle 18 that extends across the top of the closure 2. The inlet spigot 12 has a tapered outer surface which mates with a female connector 45 that is connected to the suction catheter 11. The outlet recess 23 is tapered outwardly towards its upper end to receive therein, as a mating fit, a male connector 46 that is connected to the vacuum pump 21. The connectors 45 and 46 are differently shaped and the recesses 13 and 23 are of different diameters so that it is not possible to fit the connectors into the wrong recesses. At opposite ends of the handle 18, plugs 14 and 24 are attached by means of short flexible webs 15 and 25, one of the plugs 14 being shown inserted in Figure 2. One side of each plug 14 and 24 is hollow and formed with a central nose 16 and 26, the external diameter of each plug being such that it is a close, push fit within the recess 13 and 23 with the nose being a close

sealing fit within the respective spigot 12 and 22. The other side of each plug 14 and 24 has a shallow convex surface 17 and 27 respectively. The plugs 14 and 24 can be inserted into their adjacent recess 10 or 20 by bending and twisting their web 15 and 25 so that the convex surface 17 or 27 forms a smooth, shallow projection from the handle which cannot be gripped easily. This prevents the plugs being pulled out readily once inserted.

The inlet 10 opens into an expansion chamber 30 formed in the top closure 2 and seen most clearly in Figure 3. The chamber 30 has a base plate 31 of convex shape which underlies the inlet 10 so that liquid from the inlet flows outwardly and down the edge of the plate. The diameter of the plate 31 is slightly less than that of the jar 1 so that an annular gap is formed around the outer edge of the plate, between the inner surface of the jar, which provides an outlet from the chamber 30 offset laterally from its inlet 10. Radial slots 33 are spaced around the edge of the plate 31 to provide additional liquid flow paths into the jar. The purposes of the expansion chamber 30 is to reduce turbulence and splashing inside the jar 1 by providing an indirect and smooth flow of liquid from the expansion chamber into the jar.

The spigot 22 of the vacuum outlet 20 opens into a filter assembly 40 in the top closure 2. The filter assembly 40 has a housing 44 containing a hydrophobic filter element 41 of the kind sold by Arbor Technologies under the trade mark CONTAIN and the code number 85005. The element 41 is shown in more detail in Figure 4 and is a membrane made up of two layers 141 and 142 bonded together around their edge 143. The layer 141 facing the inside of the jar 1 comprises a PTFE membrane 144 laminated with a polypropylene support screen 145, the PTFE membrane facing outwardly. This layer is tested to withstand water breakthrough at at least 10 psi. The layer 142 facing the pump 21 is a glass microfibre 146 which is laminated on both sides with polypropylene monofilament 147 and 148 that is treated to render it hydrophobic. The element 41 is retention rated at a particle size of 0.3 micron and can withstand pressure across it of 700 mm Hg. Although different forms of filter element may be effective at removing bacteria at low pressure, at the relatively high pressures encountered in surgical suction systems, a membrane type of element, such as of the kind described, is most effective. The element 41 is supported on both sides by ribs 42 formed internally of the housing 44. On its lower side, the filter assembly 40 communicates with a short vertical vent tube 43 that projects downwardly of the housing 44 into the jar 1 by a short distance, the lower end of the vent tube defining the maximum filling volume of the jar. The element 41 thereby communicates with the jar 1 without the interposition of any separate value or overflow prevention device.

When the pump 21 is turned on, it draws air out of the container through the filter assembly 40 which acts as a bacterial filter to prevent contamination of the pump or atmosphere. The reduced pressure inside the container causes suction to be applied to the suction inlet 10 and hence to the suction catheter 11. This in turn causes any liquid or small debris in the region of the operative tip of the catheter 11 to be sucked along the catheter, through the inlet 10 and the expansion chamber 30 into the container until the level of contents in the jar 1 reaches the lower end of the vent tube 43. When this happens, liquid is drawn up the tube 43 into the filter assembly 40. Although the filter element 41 allows passage of gas, it prevents the passage of liquid, so that the contents of the container are prevented from reaching the vacuum outlet 20. Because further gas flow to the vacuum pump 21 is prevented, suction ceases at the catheter 11, signalling to the user that the container is full. The user then turns off the pump and disconnects the inlet 10 and outlet 20 from their connections, thereby allowing liquid in the filter assembly 40 and tube 43 to flow back down into the jar 1. The plugs 14 and 24 are then pushed into the respective recesses 13 and 23 to seal the jar 1 closed.

The hydrophobic filter serves the dual function of preventing overfilling and of removing bacteria from gas vented from the container. It avoids the need to provide a separate bacterial filter, thereby simplifying the setting up of the suction system. There is a risk, where a separate bacterial filter is used, that replacement of the filter will be overlooked and that a filter may be left in the system long enough to become damaged. In the present arrangement, because the filter is disposed of every time the collection jar is full, there is less risk of contamination caused by use of a damaged filter. The use of a membrane type filter element enables effective bacterial filtering at the relatively high pressure differentials of about 500 mm Hg encountered in surgical suction systems.

Claims

1. A medico-surgical container having an inlet for connection to a suction catheter and an outlet for connection to a vacuum pump, characterised in that the container includes a filter (41) located in the container in line with the outlet (20), and that the filter (41) allows passage of gas from the container to the outlet (20) but prevents passage of

bacteria and of liquid such that overfilling of the container is prevented by the filter (41).

2. A container according to Claim 1, characterised in that the filter (41) is contained within a housing (44) having a tube (43) projecting downwardly into the container, the lower end of the tube (43) defining the maximum filling level of the container.

3. A container according to Claim 1 or 2, characterised in that the filter (41) includes a layer comprising a PTFE membrane (144) on a support screen (145).

4. A container according to any one of the preceding claims, characterised in that the filter (41) includes a layer (142) including a glass microfibre (146) laminated to a polymer monofilament (147, 148).

5. A container according to any one of the preceding claims, characterised in that the inlet (10) and outlet (20) are located in recesses (13 and 23), and that the container includes plugs (14 and 24) shaped for insertion in the recesses (13 and 23) to seal off the inlet (10) and outlet (20) and to form a smooth surface of the recess making subsequent removal of the plug difficult.

6. A container according to Claim 5, characterised in that the plugs (14 and 24) are each attached to the container by means of a flexible web (15 and 25).

7. A container according to any one of the preceding claims, characterised in that the container includes an expansion chamber (30) beneath the inlet (10).

8. A container according to Claim 7, characterised in that the expansion chamber (30) has a base plate (31) of convex shape located such that liquid from the inlet (10) flows outwardly and down the edge of the plate (31).

9. A container according to Claim 8, characterised in that the outlet (32, 33) from the expansion chamber (30) is at the edge of the base plate (31).

10. A container according to Claim 9, characterised in that the outlet from the expansion chamber (30) includes slots (33) formed at the edge of the base plate (31).

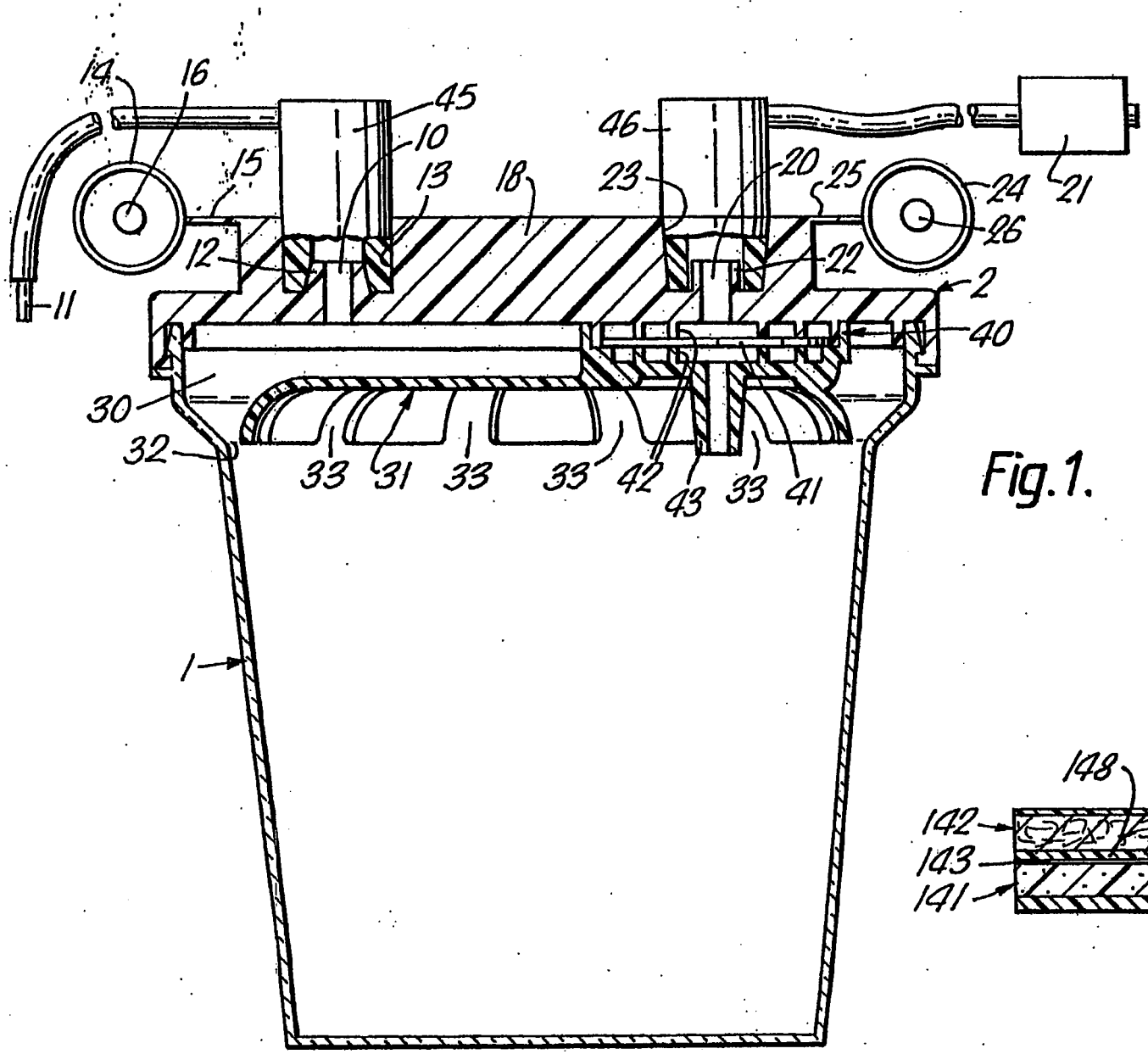
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Fig.1.

Fig.4.

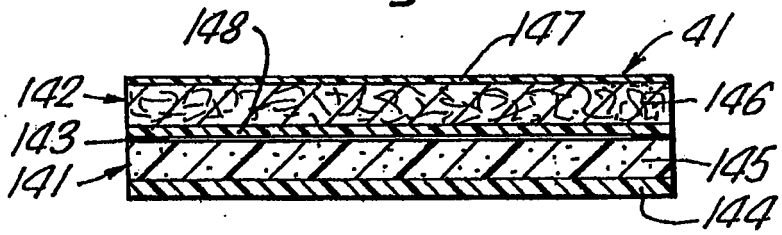
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Fig.2.

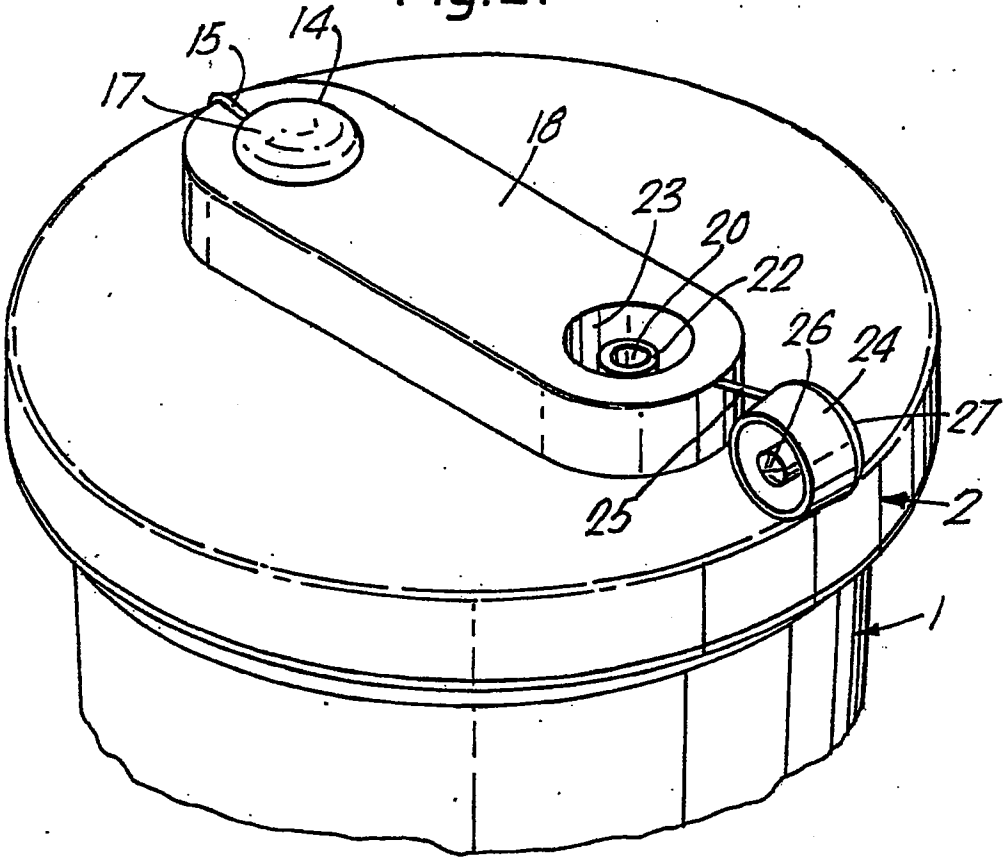
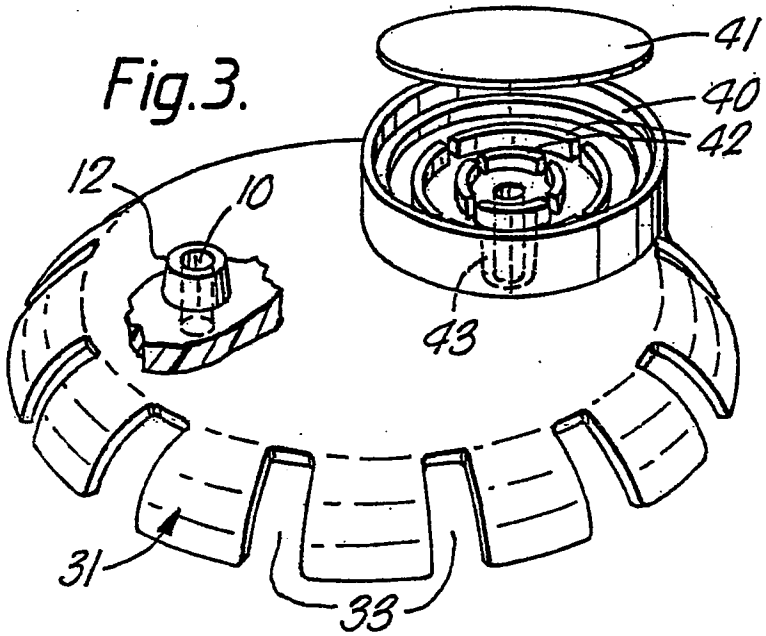


Fig.3.



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Urkunde Certificate Certificat

Es wird hiermit bescheinigt, daß für die in der beigefügten Patentschrift beschriebene Erfindung ein europäisches Patent für die in der Patentschrift bezeichneten Vertragsstaaten erteilt worden ist.

It is hereby certified that a European patent has been granted in respect of the invention described in the annexed patent specification for the Contracting States designated in the specification.

Il est certifié qu'un brevet européen a été délivré pour l'invention décrite dans le fascicule de brevet ci-joint pour les Etats contractants désignés dans le fascicule de brevet.

Europäisches Patent Nr. **European Patent No.** **Brevet européen n°**

1018967

Patentinhaber **Proprietor of the Patent** **Titulaire du brevet**

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München, den
Munich,
Fait à Munich, le 18.08.04

Alain Pompidou

Präsident des Europäischen Patentamts
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(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 1 018 967 B1

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention of the grant of the patent:
18.08.2004 Bulletin 2004/34

(21) Application number: **98941623.5**

(22) Date of filing: **09.09.1998**

(51) Int Cl.[7]: **A61B 19/08**

(86) International application number:
PCT/GB1998/002713

(87) International publication number:
WO 1999/013793 (25.03.1999 Gazette 1999/12)

(54) SUCTION HEAD FOR WOUND TREATMENT AND COMBINATION WITH A SURGICAL DRAPE

SAUGKOPF ZUR WUNDBEHANDLUNG UND KOMBINATION MIT EINEM CHIRURGISCHEN ABDECKTUCH

BEC D'ASPIRATION POUR LE TRAITEMENT DES PLAIES ET COMBINAISON AVEC UN CHAMP STERILE

(84) Designated Contracting States:
AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU NL PT SE

(30) Priority: **12.09.1997 GB 9719520**

(43) Date of publication of application:
19.07.2000 Bulletin 2000/29

(60) Divisional application:
04009482.3 / 1 440 667

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(56) References cited:
EP-A2- 0 117 632
US-A- 5 437 622
WO-A1-97/18007
US-A- 5 636 643

EP 1 018 967 B1

Printed by Jouve, 75001 PARIS (FR)

therefore, there is provided a suction head for applying suction to a wound area which comprises a generally planar flange portion and a tubular connector piece on a first face, for connecting a suction tube to an aperture through the flange portion to the other face, said other face having projections defining flow channels facilitating flow of fluid towards said aperture.

[0014] Preferably, the suction head described above is combined with a surgical drape, the drape comprising a thin, flexible, adhesive-coated plastics film, and the tubular connector piece extends through an opening in the plastics film with the adhesive coating adhered to said first face of the flange portion.

[0015] Preferably, the suction head is used in conjunction with an open-celled foam pad so that one surface of the foam pad is placed in contact with a wound area and the suction head applied to the other surface of the foam pad. In the case of deep wounds the foam may be shaped and placed so that it is packed into the wound cavity as described in our above cited PCT applications. According to another technique, which is particularly applicable to superficial wounds, the foam pad may be a relatively thin pad which is placed over the wound. The suction head is placed in contact with the open face of the foam pad and the drape applied over the suction head to fix the assembly to the patent's skin.

[0016] Various types of open celled foams can be used as described in our above cited PCT applications. The foam may be a polyurethane foam but polyvinyl acetate (pva) foams are preferred, especially when used as a pad which is placed over the wound. These are to some extent hydrophilic, which seems to exhibit beneficial comfort properties when applied to the skin. Wound healing is stimulated by maintenance of moist conditions in the wound area, and this is facilitated by using a hydrophilic foam.

[0017] Further features and advantages of the present invention will be apparent from the following description and accompanying drawings, of non-limiting examples in accordance with the invention.

[0018] Referring to the accompanying drawings:-

Figure 1 represents a conventional design of surgical drape;

Figure 2 represents a variation in the design of the handling bars at one end of the drape shown in Figure 1;

Figure 3 is a view similar to Figure 1 of a surgical drape in accordance with the invention;

Figure 4 is a plan view of the surgical drape shown in Figure 3;

Figure 5 is a plan view from beneath of a suction head in accordance with the invention; and

Figure 6 is a side elevation of the suction head shown in Figure 5;

Figure 7 is a view similar to Figure 6 but shows the suction head secured to a skin surface with the drape and with a foam pad located between the head and the skin surface.

Figure 8 is a perspective view of the drape with a central strip portion of the protective sheet in the course of being removed, and

Figures 9(a)~9(c) illustrate the steps of affixing the dressing assembly to a wound area on a patient's leg and attachment to a negative pressure assembly.

[0019] Referring to Figures 1 and 2 of the accompanying drawings, a conventional laminate for use as a surgical drape comprises a thin, flexible, transparent plastics film 1 which is adhesive-coated on one face 2, normally with a high-tack pressure-sensitive adhesive, and is protected with a releasable layer 3. The thin plastics film is conveniently of polyurethane because it transmits moisture. Layer 3 is normally considerably thicker than film 1 and is coated on the surface adjacent to the adhesive with a releasable material such as a silicone to facilitate stripping away from the adhesive-coated film.

[0020] In order to facilitate removal of the adhesive-coated film prior to use of the device, handling bars 4 are bonded at each end to the adhesive-coated film 1. Thus, by holding one of the bars 4, the protective layer 3 can be stripped off and the adhesive face applied to the skin of the patient. To facilitate handling of the thin, flexible film 1, a strengthening plastics film 5 is frequently applied to the free face of the plastics film 1. This is generally also transparent or translucent. Film 5 is preferably not bonded with adhesive to film 1, but may remain in contact by reason of electrostatic forces or because of close contact between the two conforming surfaces of film 1 and film 5.

[0021] Usually, the surgeon or nurse will wish to strip off the protective layer 5 after the film 1 has been correctly placed on the patient's skin, and this can be facilitated by making partial cuts 6 through the films 1 and 5, so that as the handling bar 4 is drawn upwards from the patient's skin, the adhesive film 1 remains adhered to the patient, while the partial cuts 6 causes separation of the flexible film from the strengthening film 5. Strengthening bars 7 may be provided to hold the lateral edges of the strengthening film 5 and film 1 together with their main parts.

[0022] An alternative arrangement is shown in Figure 2, in which the strengthening film 5 is provided with a separate overlapping handling bar 14, to facilitate its removal from the flexible film 1.

[0023] Further details of the make-up and manufacture of surgical drapes are given in US Patent No. 5,437,622 and European Patent Application No. 0161865 and the prior art referred to therein.

[0024] Referring to Figure 3 and 4, the surgical drape of this invention comprises a protective outer film 20, laminated to a thin, flexible film 21. The flexible film 21 includes an adhesive-coated layer which is protected with a release-coated sheet material 24. Lateral edges

2. A suction head as claimed in claim 1 which is combined with a surgical drape, the drape comprising a thin, flexible adhesive-coated plastics film (21), the tubular connector piece (35) extending through an opening in the plastics film (21) with the adhesive coating adhered to said first face of the flange portion (30).

3. A suction head and surgical drape combination as claimed in claim 2 in which the adhesive-coated film (21) is strengthened with a second plastics film (20) which is thicker or less flexible than said adhesive coated film.

4. A suction head and surgical drape combination as claimed in claim 2 or 3 wherein the adhesive coating on said flexible film is protected with a protective, releasable layer (24) covering the area of the adhesive, said releasable layer comprising a separate strip protecting the adhesive coating in the vicinity of the suction head and said strip carrying a flap (27) overlapping an adjacent portion of the releasable layer and constituting a handle to facilitate removal of said strip prior to use.

5. An assembly for use with a source of suction for stimulating healing of wounds which comprises a foam pad comprising an open-celled flexible polymer foam and a suction head and drape as claimed in claim 4.

6. A suction head according to claim 1 in combination with a surgical drape which comprises a thin, flexible, adhesive-coated plastics film (21) and a strengthening layer (20) applied to the face opposite to the adhesive coating, the strengthening layer being a plastics film which is thicker or less flexible than said adhesive-coated film, and a protective, releasable layer (24) applied to the adhesive coating, the drape having an aperture (25) through at least the strengthening film and adhesive-coated film to permit, in use, access to a wound area, at least one first edge of the drape having a non-adhesive coated handling bar (23) for separating the adhesive-coated film from the protective layer, and wherein the protective layer comprises a separate strip extending parallel to the first edge of the drape, and which protects the adhesive coating in the region of the aperture (25) and carries at least one flap (27) overlapping the adjacent portion of the protective layer, said flap constituting a handle for facilitating removal of said strip prior to use.

Patentansprüche

1. Saugkopf zum Anwenden von Unterdruck an einen Wundenbereich, der umfasst:

einen im Wesentlichen planaren Flanschabschnitt (30) und ein röhrenförmiges Verbindungsstück (35) auf einer ersten Fläche zur Verbindung eines Saugrohrs (106) mit einer Öffnung (25) durch den Flanschabschnitt (30) zu der anderen Fläche;

dadurch gekennzeichnet, dass die andere Fläche Überstände (32) aufweist, welche Durchflusskanäle (33) definieren, die Durchfluss von Fluiden zu der Öffnung erleichtern.

2. Saugkopf nach Anspruch 1, der mit einer medizinischen Abdeckung kombiniert ist, wobei die Abdekkung eine dünne, flexible, mit Haftmittel beschichtete Kunststofffolie (21) umfasst, und sich das röhrenförmige Verbindungsstück (35) durch eine Öffnung in der Kunststofffolie (21) erstreckt, wobei die Haftmittel-Beschichtung an der ersten Fläche des Flanschabschnitts (30) anhaftet.

3. Kombination eines Saugkopfs mit einer medizinischen Abdeckung nach Anspruch 2, bei der die mit Haftmittel beschichtete Folie (21) durch eine zweite Kunststofffolie (20) verstärkt wird, die dicker oder weniger flexibel als die mit Haftmittel beschichtete Folie ist.

4. Kombination eines Saugkopfs mit einer medizinischen Abdeckung nach Anspruch 2 oder 3, wobei die Haftmittel-Beschichtung auf der flexiblen Folie von einer schützenden, ablösbaren Schicht (24) geschützt ist, die den Bereich des Haftmittels abdeckt, und wobei die ablösbare Schicht einen separaten Streifen umfasst, der die Haftmittel-Beschichtung in der Nähe des Saugkopfs schützt und der eine Lasche (27) trägt, die einen angrenzenden Abschnitt der ablösbaren Schicht überlappt und einen Griff bildet, um die Entfernung des Streifens vor Gebrauch zu erleichtern.

5. Anordnung zum Gebrauch mit einer Quelle für Unterdruck zum Anregen von Wundheilung, die umfasst: ein Schaumstoffpolster, das einen offenzelligen flexiblen Polymer-Schaumstoff umfasst, und einen Saugkopf sowie eine Abdeckung nach Anspruch 4.

6. Saugkopf nach Anspruch 1 in Kombination mit einer medizinischen Abdeckung, die umfasst:

eine dünne, flexible, mit einem Haftmittel beschichtete Kunststofffolie (21),
und eine Verstärkungsschicht (20), die an der der Haftmittel-Beschichtung gegenüberliegenden Fläche angebracht ist, wobei die Verstärkungsschicht eine Kunstofffolie ist, die dicker oder weniger flexibel als die mit Haftmittel be-

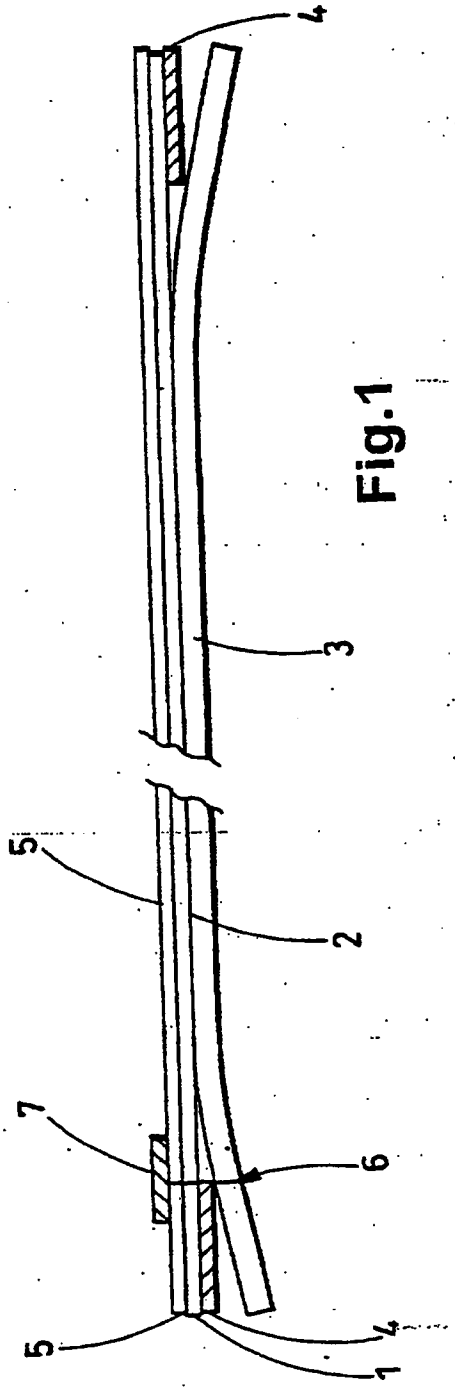

Fig.1

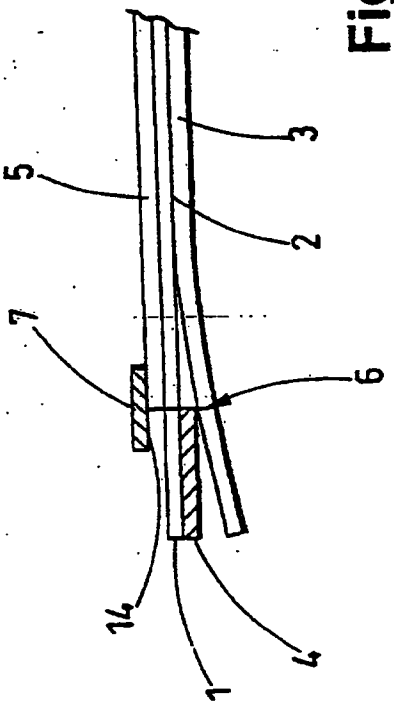

Fig. 2

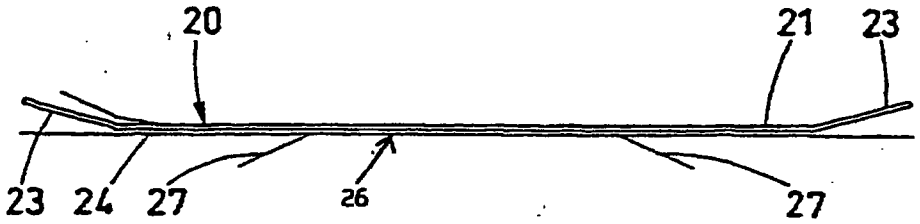

Fig. 3

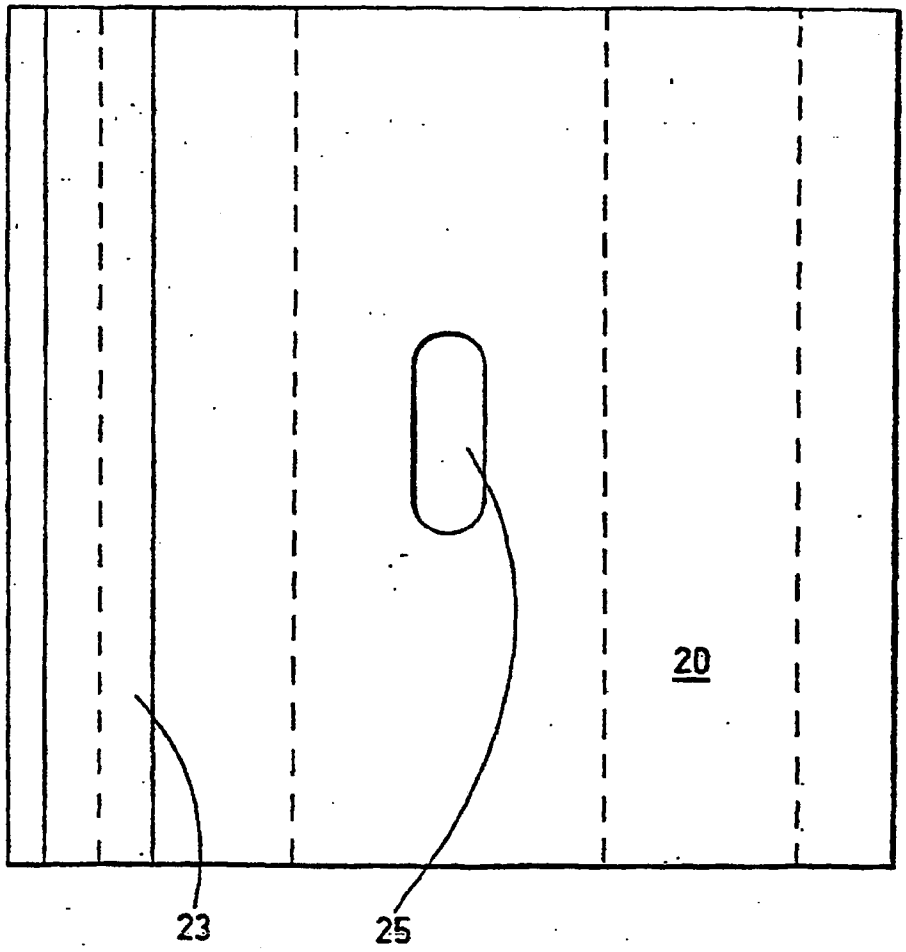

Fig. 4

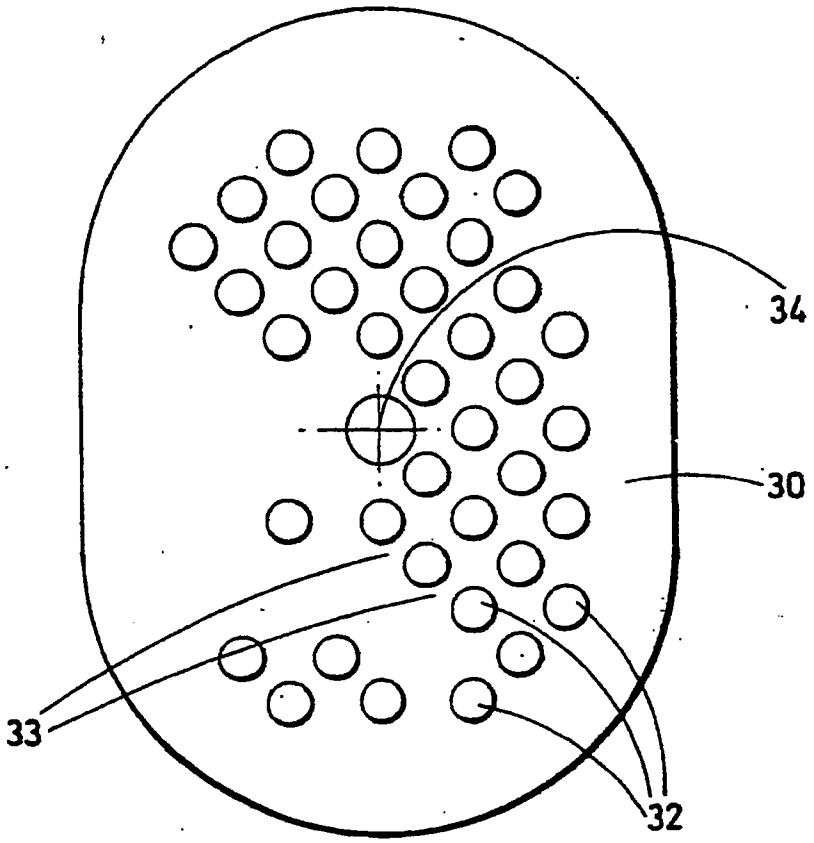

Fig. 5

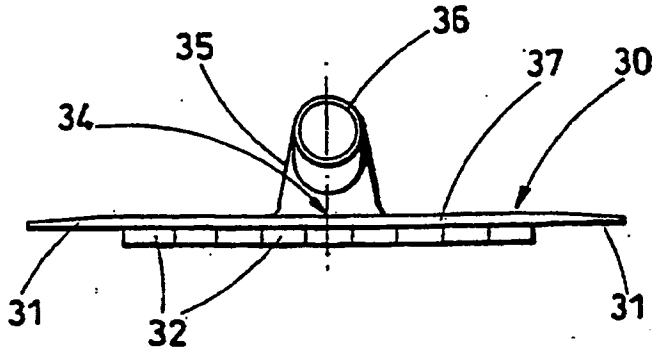

Fig. 6

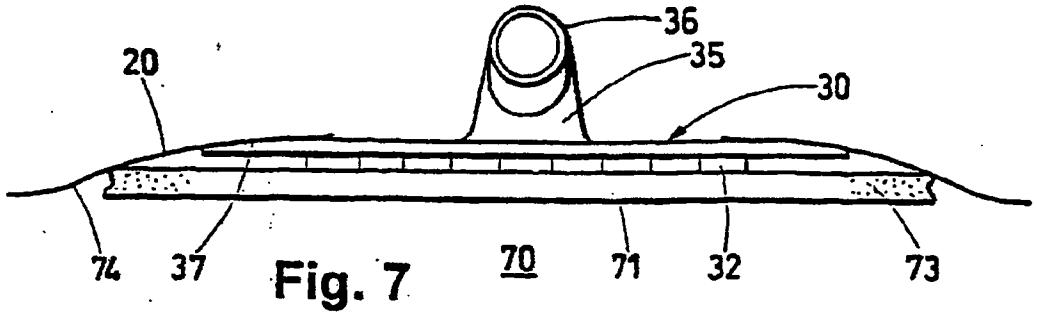

Fig. 7

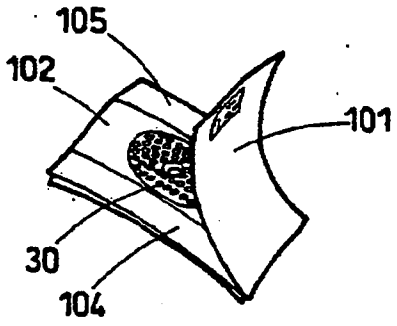

Fig. 8

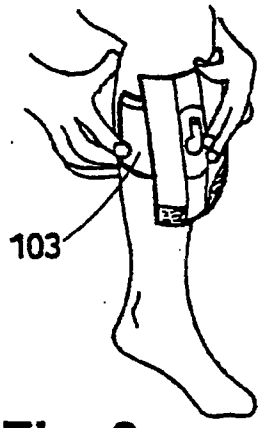

Fig. 9a

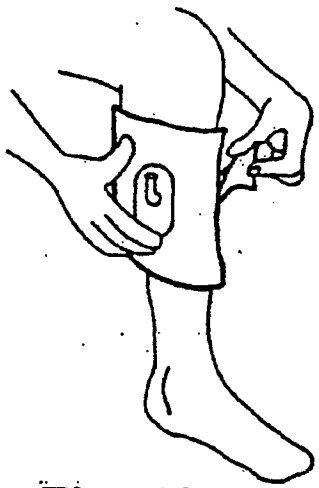

Fig. 9b

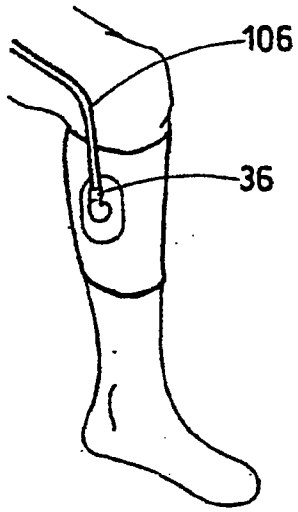

Fig. 9c

BALANCE DEVICE

Patent number:	JP4129536
Publication date:	1992-04-30
Inventor:	KEINO HIROYOSHI
Applicant:	TERUMO CORP
Classification:	
- international:	A61B5/14; A61M1/02; G01G17/04
- european:	
Application number:	JP19900247288 19900919
Priority number(s):	JP19900247288 19900919

Abstract of **JP4129536**

PURPOSE:To obtain a balance device with which the balance precision is improved, by correcting the detection error of a weight detecting means which is caused by the tilt of a container supporting part, according to the tilt of the container supporting part, and installing a control means for obtaining the weight in a container on the container supporting part. CONSTITUTION:As for a blood taking device 10, a bag receiving plate 19 is supported on a balance 33 which is cantilever-supported through a balance installation member 31, and the CPU 65 of a main control circuit 61 detects the weight of a blood bag 1 on the bag receiving plate 19 in the vertical direction for the hag receiving plate, from the output V2 of a weight detecting sensor 34 consisting of a strain guage on the basis of the torsional deformation of the balance 33. Further, the CPU 65 of the main control circuit 61 calculates the tilt angle theta which the bag receiving plate 19 forms for the vertical direction in the case when a weight detection sensor 34 detects weight, from the output V1 of a tilt detection sensor 100 installed on the bag receiving plate 19 or a swing frame 22. The CPU 65 of the main control circuit 61 detects the correct weight of the blood bag 1 by correcting the output V2 of the weight detection sensor 34 by using the tilt angle theta, and the blood taking-in quantity is measured.

PATENT SPECIFICATION

692,578

Date of Application and filing Complete Specification: Sept. 4, 1950.
No. 21734/50.
Application made in United States of America on Sept. 13, 1949.
Complete Specification Published: June 10, 1953.

Index at acceptance:—Classes 81(ii), B14; and 94(i), G1f.

COMPLETE SPECIFICATION

Improvements in or relating to Drape Sheets for Surgical Use

We, MINNESOTA MINING AND MANUFACTURING COMPANY, a corporation organised under the laws of the State of Delaware, United States of America, of 900, Fauquier Avenue, City of St. Paul, State of Minnesota, United States of America, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates to a sterile-packaged adhesive-coated drape sheet especially adapted for utilization in surgical operations, for dressing wounds, and for kindred uses.

The present invention provides a sterile-packaged drape sheet characterized by comprising: (1) a surgically-sterile adhesive-coated surgical drape sheet formed of a synthetic plastic film sheet which is soft and pliable so as to be readily draped over the contours of the human body, a normally tacky pressure-sensitive adhesive bonded to a relatively small portion of said film so as to provide a skin-adhering area adjacent to a surgical operative site when the drape sheet is applied to a body, the major portion of the drape sheet being adapted to cover a relatively large adjoining skin area without adhering thereto, the film and the adhesive being waterproof and resistant to body fluids and being substantially non-toxic to the human skin; (2) a backing sheet or liner temporarily covering the tacky adhesive area and being removable therefrom without causing offsetting of the adhesive from the film sheet; (3) a sealed package enclosing said drape sheet and adapted to maintain the latter in a surgically sterile condition, the composite sealed package containing the surgical drape sheet having been sterilized as a unit so as to insure a surgically-sterile condition of the drape sheet therein, said drape sheet being unharmed by said sterilization and being ready for removal and immediate use by a surgeon whenever desired, without further sterilization being required.

It is essential in surgery that the skin area of the patient adjacent the incision be as nearly sterile as possible and like considerations apply in the case of wound dressings. We have found that this condition may be more easily maintained by making use of a sterile-packaged drape sheet comprising a thin, soft, pliable, water-resistant body or film that can be made to adhere to the skin over, around or in the vicinity of the wound or the area where the operation is performed. Accordingly, our drape sheet is provided on at least part of one side with a pressure-sensitive adhesive capable of adhering firmly both to the film and to the patient's skin. The adhesive film and any other elements making up the drape sheet, together with the package containing them, are sterilized as a unit and kept sterile until the drape sheet is to be used.

After the desired body surface area of the patient has been suitably prepared, the sterile package so made up is opened and application of our drape sheet is made. For surgical uses, such sheet may and usually will have a preformed opening therein, but, if desired, it may be left intact so that a surgical incision may be made directly therethrough, the operation being carried out in either case in much the usual manner. For use as a wound dressing, the sheet will usually be left intact, but, if desired, may be provided with a preformed opening or incised as necessary. Even relatively long incisions or wounds may effectively be closed without stitches or sutures and without clips by applying one or more adhesive-coated tapes to the drape sheet across the incision or wound in order to hold the same closed during healing. The drape sheet adheses firmly to the skin

and, being water-resistant, is not affected to any great extent by body fluids.

By use of our sterile-packaged drape sheet in these and like ways, chances of infection are reduced, scars minimized, and desirable healing conditions maintained.

It is among the objects of our invention to provide a sterile-packaged drape sheet that is particularly adaptable for surgical and like uses. Other objects include the provision of a sterile surgical covering lending itself to necessary handling without needless contamination of the covering; the provision of a sterile adhesive-coated film with an associated supporting base or backing sheet for the adhesive which film is susceptible of long storage life without deterioration, of being easily cut to a desired shape, and of being readily separated from the supporting base or backing sheet prior to use, and the provision of a folded adhesive-coated pellicle which, together with the package containing it, may be subjected as a unit to sterilizing temperatures without developing undue softening, oozing, sticking or undesired changes in the physical properties of any component elements of the unit. Other objects of the invention will appear from the detailed description which follows of certain of the preferred embodiments thereof.

For an understanding of our invention, reference may be had to the accompanying drawings, in which:

Figure 1 is an isometric view showing the drape sheet of the invention as it appears after having been folded, sealed in an inner wrapper, sterilized, and enclosed in an outer wrapper;

Figure 2 is an isomeric view of the sealed inner wrapper containing the drape sheet as it appears after removal of the outer wrapper;

Figure 3 is an isometric view of a partly unfolded drape sheet after its removal from the inner wrapper, such view showing the drape sheet as square in shape and provided with a round preformed opening surrounded by an annular backing sheet of the nature of a liner;

Figure 4 is an isometric view showing another form of drape sheet provided with a preformed oval opening in which, as in Figure 3, such opening is surrounded in the immediate vicinity thereof by an adhesive protected by a backing sheet of the nature of a liner;

Figure 5 is a section, on an enlarged scale, on line 5—5 of Figure 4;

Figure 6 is a similar section showing the tab pulled up from its normal position on the drape sheet;

Figure 7 is a similar section showing the tab and a considerable part of the backing sheet pulled away from the drape sheet, in part exposing the adhesive;

Figure 8 is a fragmentary isometric view similar to Figure 5 showing the drape sheet after the backing sheet has been completely pulled away from it;

Figure 9 is an isometric view showing still another form of drape sheet, the same being carried by a relatively stiff supporting base of the nature of a liner from which part of the drape sheet is shown as having been peeled back;

Figure 10 is an enlarged fragmentary isometric view looking in the direction indicated by arrows 10—10 of Figure 9, and

Figure 11 is an enlarged fragmentary isometric view similar to that of Figure 10 but reversed to show the details of the bottom of the supporting base.

As indicated in Figures 1 to 3, in addition to the drape sheet itself, the sterile-packaged drape sheet of the invention preferably makes use of an inner wrapper in which the drape sheet is inserted, sealed and sterilized, and, of somewhat larger dimensions than the dimensions of the inner wrapper, an outer wrapper in which the inner wrapper, with drape sheet enclosed, is inserted and within which it is sealed to protect the inner wrapper and the enclosed drape sheet against contamination. If, as may but need not necessarily be the case, the drape sheet includes a supporting base or backing sheet that is substantially coextensive with an associated layer of pressure-sensitive adhesive, the form or nature thereof may be revealed in relief or be visible through the material comprising the inner wrapper; similarly, notwithstanding the presence on the surface of the outer wrapper of printing to show a trade mark or, for example, instructions for use, the form of the inner wrapper may and usually will be apparent through the outer wrapper. These conditions are illustrated in Figures 1 and 2.

In Figure 1, A designates the outer wrapper, the same having an integral end flap B forming part thereof which has been folded over onto the body portion of the outer wrapper A and sealed in position by a strip of transparent tape C provided on its inner face with an application of a water-resistant or waterproof heat-sealing adhesive of one of the types known in the packaging art. Appearing through the material comprising outer

wrapper A, which conveniently may be of Cellophane (Registered Trade Mark), glassine, wax-coated paper or some similar transparent or translucent material, is inner wrapper D. The latter, shown to better advantage in Figure 2, is similar to outer wrapper A in that it includes an end flap which has been folded over onto the body portion of the wrapper and sealed in position by a strip of transparent tape carrying a like heat-sealing adhesive. Within the confines of inner wrapper D is the drape sheet E, the same being represented as having been folded. Figure 3 shows drape sheet E as partially opened out following its removal from inner wrapper D, a single fold remaining to be opened out being indicated in dotted lines as underlying the main portion of the drape sheet.

In the form shown in Figure 3, drape sheet E, which is square in shape, includes a round central opening immediately surrounded by an annular backing sheet overlying a ring of pressure-sensitive adhesive; however, these details, in and of themselves, are not necessarily features of the invention insofar as it relates broadly to sterile-packaged drape sheets.

In practice, the drape sheet, if of a size requiring folding, is folded as necessary, inserted in inner wrapper D and sealed by closing the end flap and applying to it the strip of transparent tape carrying the heat-sealing adhesive. The inner wrapper, with the drape sheet enclosed, is then subjected to sterilization in an autoclave, as, for example, for thirty minutes at 250° F. Thereafter, inner wrapper D is removed from the autoclave, inserted in outer wrapper A, and sealed within the latter by applying tape C to flap B. The whole may be shipped, stored and sold in the form illustrated in Figure 1, being opened only when contemplated use of the drape sheet makes it necessary. Thus a sterile drape sheet is available when required for emergency use in circumstances in which sterilizing equipment may be and frequently is lacking.

The drape sheet itself preferably comprises a waterproof body portion of thin, soft, pliable, membranous, somewhat stretchable, more or less transparent, non-porous, non-toxic film. For surgical and like uses, the thickness may vary from about .001" to about .006". Part or all of one side of the film is coated with a very thin, non-toxic, water-resistant or waterproof pressure-sensitive adhesive which adheres tenaciously to the surface of the film. Such adhesive should be able to withstand normal sterilizing temperatures without softening, oozing out or undergoing other substantial changes in its physical properties, in addition to which it should preferably be transparent, normally tacky and water-insoluble, so that no moistening or other treatment will be necessary to bring the adhesive into condition for use. Co-extensive with the body portion or at least with the part thereof which is coated with adhesive is a backing sheet or supporting base which to some extent serves as a liner, particularly when the drape sheet is folded.

In the embodiment of the drape sheet illustrated in detail in Figures 4 to 8, drape sheet F takes the form of a large oblong body portion 1 having therein a transversely extending oval opening 2 surrounded by a small, relatively stiff backing sheet 3, likewise oval in shape, of such dimensions as to overlie body portion 1, overlapping it by about 1½ inches around the edges of opening 2 after the fashion of an elliptical annulus. Between body portion 1 and backing sheet 3 is a pressure-sensitive adhesive, designated 4, which is so formulated in accordance with practices known in the adhesives art that, when employed between body portion 1 and backing sheet 3, it will adhere to both but in the event of intentional separation of the two will have a preferential affinity for body portion 1. Thus it may be applied to body portion 1 before backing sheet 3 is applied to it or, preferably, applied first to backing sheet 3 and then, along with backing sheet 3, applied to body portion 1 in such manner as to form an intervening layer. The opening 2 in body portion 1 and the registering opening in backing sheet 3 may, if desired, be formed before the two are brought into juxtaposition but conveniently may be punched out at one time after the assembly is otherwise complete.

Backing sheet 3, usually of a material that is relatively stiff and often, but not necessarily, thicker than body portion 1, is provided in order to protect adhesive coating 4, which it does by serving as a supporting base or temporary carrier. It enables the film comprising body portion 1 to be handled prior to actual use without likelihood of damage or distortion, particularly in the vicinity of opening 2. As illustrated, backing sheet 3 is formed of a somewhat flexible, preferably waterproof or waterproofed material, which, as distinguished from body portion 1, usually will be non-stretchable.

Ordinarily, but not necessarily in every case, backing sheet 3 will be creped or embossed to provide a plurality of adjacent relatively raised and depressed

areas on its inner surface, in which case the raised portions of the inner surface are likely to appear as depressed portions on the outer surface and, to some extent as depressed portions on the opposite or uncoated side of body portion 1. The pattern of these areas will usually be found to have been reproduced by and to be present in adhesive coating 4 after body portion 1 and backing sheet 3 have been separated as hereinafter described. The rough surface formation of backing sheet 3 facilitates separation of the backing sheet from body portion 1; similarly, its reproduction in adhesive coating 4 probably facilitates later separation of body portion 1 from the skin area to which body portion 1 is applied.

Backing sheet 3 may, if desired, be coated or otherwise treated, as with lacquer or by other suitable means, so that it will not be split or delaminated by adhesive coating 4 when it is removed from body portion 1. Backing sheet 3 is, furthermore, less responsive to adhesive coating 4 than is the surface of body portion 1, thus facilitating its removal from body portion 1 by peeling back at an angle. The surface arrangement of backing sheet 3 wherein adjacent raised and depressed areas are formed thereon is effective in bringing about easy removal of backing sheet 3 from adhesive coating 4 even when the adhesive has substantially the same adherent properties per unit of flat surface area relative to backing sheet 3 as it has to body portion 1.

As indicated in Figures 4 to 8, backing sheet 3 has a tab 5 for use in initiating separation of backing sheet 3 and body portion 1. Such tab may be provided by applying the desired adhesive to the inner surface of backing sheet 3, then masking part of the adhesive by means of a strip of smooth-surfaced paper 6 that, when applied, serves to cover the adhesive to an extent sufficient to permit the edge of backing sheet 3 to be manipulated freely, and finally locating backing sheet 3 in the desired position on body portion 1 with adhesive coating 4 between them. Thereafter backing sheet 3 may be grasped by tab 5 and stripped or pulled away from body portion 1, leaving exposed thereon so much of adhesive coating 4 as was not masked off by paper 6. The latter sequence of steps is illustrated in stages in Figures 6 to 8, inclusive.

Body portion 1, with adhesive coating 4 down, is then applied to the skin area of the patient around the wound or incision, if there is one, or to the skin area in which the incision is to be made. If, as in the embodiment of the invention shown in Figures 4 to 8, body portion 1 is provided in the middle thereof with a symmetrically located opening 2, the latter is centered along or around the wound or incision. Obviously, however, back-sheet 3 and adhesive coating 4 need not necessarily be located around a central opening in body portion 1 but may be located around an opening near one of the ends or may extend linearly along one of the lateral limits thereof, preferably with a tab similar to tab 5 projecting beyond or underlying the edge of body portion 1. In such cases, the drape sheet is so applied to the body of the patient that adhesive coating 4 will be in juxtaposition to the wound or incision and body portion 1 will extend away therefrom in the desired direction.

In the embodiment of the invention illustrated in Figures 9, 10 and 11, drape sheet G takes the form of a film 11 to which a pressure-sensitive adhesive coating 12 has been applied, over most but less than all of one face thereof, as by transfer or off-setting from a supporting base 13. Originally, for example, the adhesive coating may be in contact with supporting base 13 over the greater part of the upper surface of the latter, not including a linearly extending strip at one of its lateral limits. If a similarly shaped film 11 is applied thereto, it will be in contact with the adhesive over all of the lower surface thereof except for a like linearly extending strip, thus leaving an uncoated marginal area 14 by which film 11 may be grasped and manipulated, as in peeling it off supporting base 13. As illustrated in Figures 9, 10 and 11, base 13 takes the form of a diamond-embossed sheet of somewhat stiff supporting paper-like material from which film 11 and adhesive coating 12 may be peeled off simultaneously without leaving any substantial part of adhesive coating 12 on supporting base 13. Once stripped from supporting base 13, film 11 and adhesive coating 12, with the latter down, are applied to the skin area of the patient in the vicinity of the intended incision, which in such case is made directly through body portion 11.

The use of one form or another of our sterile-packaged drape sheet usually eliminates the necessity for using wound towels of the conventional type. If desired, especially with a large drape sheet of the kind illustrated in Figures 4 to 8, excess material may be cut away therefrom after the operation or treatment or, if desired, folded over onto itself to form a bundle which can be made fast over the incision or wound by means of tape strips. By applying a small drape

sheet, as, for example, a drape sheet of the type shown in Figures 9 to 11, directly over the area of an incision after the operation is completed and the incision closed, dressings may be largely eliminated. Inasmuch as the films comprising the body portions of the drape sheets are preferably more or less transparent; i.e., transparent at least when in immediate contact with the flesh, a surgeon can easily determine, in the first instance, where to make an incision and can watch a wound or incision during healing and make any necessary incisions or punctures for drainage, etc. The adjacent skin area is protected from contact with drainage products and thus irritation and possible infection are prevented.

As previously indicated, the film of which the body portion of our drape sheet is formed is preferably a membraneous film that is thin, soft, pliable, and characterized, by virtue of its membraneous nature, by an agreeable "handle" or feel. It is desirable that it have good draping properties, particularly if the adhesive coating covers only a minor fractional part of its surface. Preferred for purposes of the invention are films that are highly transparent or, if not, at least sufficiently transparent when in immediate contact with the flesh to reveal the texture and color of the skin; however, translucent and even opaque drape sheets may be employed in many cases, if desired.

The film is preferably, but need not necessarily, be of a somewhat stretchable nature so that it may be conformed to the contour of the body area to which it is attached. Membranous films of the kinds described are usually non-porous and incapable of becoming saturated by perspiration, but in some cases semi-porous films capable of transmitting moisture vapor but not water or like liquids may be utilized to especial advantage. A film thickness or gauge of from about 0.001 to 0.006 inch (but preferably 0.004 inch) is considered best. Films of these characteristics are commercially available from a wide variety of sources.

Such films may, but need not necessarily be, of the nature of synthetic plastics, by which term as herein used are embraced such materials as synthetic polymers, synthetic elastomers, and plasticized derivatives of cellulose. Examples of synthetic polymers are polyvinyl chloride films ("Koroseal" (Registered Trade Mark),) vinylidene chloride polymer films ("Saran" (Registered Trade Mark)), films made from co-polymers of vinyl chloride and vinyl acetate ("Vinylite" (Registered Trade Mark)), and poly-ethylene films ("Polythene"), the latter particularly if modified to preclude softening at unduly low temperatures. Synthetic elastomers include synthetic rubber and rubber-like materials ("Neoprene"), rubber hydrochlorides ("Pliofilm" (Registered Trade Mark)), and the like; however, natural rubber and naturally occurring rubber-like substances are also suitable in many cases. Cellulose derivatives include, along with regenerated cellulose, cellulose esters, cellulose ethers and other derivatives of cellulose; e.g., cellulose acetate, cellulose nitrate, etc.

The preferred forms of drape sheets employ a "Vinylite" film which is transparent but contains a dye imparting a light greenish tint. It is a calendered film having a thickness of 4 mils (0.004"), formed from a copolymer of vinyl chloride and vinyl acetate, plasticized with about 32% of dioctyl phthalate. The proportion of vinyl acetate relative to vinyl chloride is believed to be in the ratio of about 4:96.

In lieu of membranous films of the types described, suitable surface-coated textile fabrics may be used in and for the body portion of the drape sheet.

The backing or supporting element may be treated or untreated fabric, natural or synthetic rubber, a synthetic plastic, or a water-resistant cellulosic material of some suitable type. Among the available types of water-resistant cellulosic materials are parchment, wax-coated paper and moisture-proof Cellophane (Registered Trade Mark). A typical fabric of a kind lending itself to use for these purposes is Holland cloth. If need be, the backing or supporting element is so treated, chemically or otherwise, as to preclude the possibility of splitting or delamination. Whatever the physical and/or chemical nature of the supporting base or backing sheet, its action is principally to protect the adhesive-coated area of the film making up the body portion of the drape sheet; accordingly, its precise nature is not usually important, so long as it serves the intended function, provided it does not break down, ooze out, or become sticky at sterilization temperatures.

The pressure-sensitive adhesive, in its preferred form, is a tacky rubber-like co-polymer of 2-ethylbutyl acrylate and ethyl acrylate in the weight ratio of 75:25 which is plasticized with triethylene glycol di-2-ethylhexoate (25 parts per 100 of the polymer). Another example is an adhesive composed of a

plasticized methacrylate; for example, isobutyl methacrylate plasticized by the addition of triethylene glycol dibutyl hexoate. The adhesive may, if desired, contain a suitable bactericide. Other than those disclosed above, various types of pressure-sensitive adhesives suitable for the purposes of the invention are known in the adhesives art and may be used in lieu of the preferred types hereinabove described.

A drape sheet so made up may be packaged in any convenient way. For example, instead of being inserted in flat or folded condition in one or more wrappers of the nature of envelopes, as in the case of the wrappers shown in Figures 1 and 2, it may be rolled and inserted in rolled form in a tubular container, in which case it and the container in which it is inserted may be sterilized as a unit and, after sterilization, wrapped, coated with a strippable film ("skin"), or inserted in a tubular container of larger dimensions. If a bactericide is packaged with the drape sheet, with or without sterilization in an autoclave, the outer wrapper, coating or container may in some cases be omitted entirely.

Although we have illustrated particular forms of our sterile-packaged drape sheet and have set out certain procedures and classes of substances which may be used by packaging it, sterilizing it, and constructing it, as, for example, materials available for the film or body portion, for the backing sheet or supporting base, and for the adhesive, it will be understood that many variations and modifications may be made therein without departing from the invention. We therefore do not wish to be limited to the exact materials, arrangements or proportions herein described or the specific surgical uses herein referred to but claim as our invention all embodiments thereof coming within the scope of the appended claims.

What we claim is:—

1. A sterile-packaged drape sheet characterized by comprising: (1) a surgically-sterile adhesive-coated surgical drape sheet formed of a synthetic plastic film sheet which is soft and pliable so as to be readily draped over the contours of the human body, a normally tacky pressure-sensitive adhesive bonded to a relatively small portion of said film so as to provide a skin-adhering area adjacent to a surgical operative site when the drape sheet is applied to a body, the major portion of the drape sheet being adapted to cover a relatively large adjoining skin area without adhering thereto, the film and the adhesive being waterproof and resistant to body fluids and being substantially non-toxic to the human skin; (2) a backing sheet or liner temporarily covering the tacky adhesive area and being removable therefrom without causing offsetting of the adhesive from the film sheet; (3) a sealed package enclosing said drape sheet and adapted to maintain the latter in a surgically-sterile condition, the composite sealed package containing the surgical drape sheet having been sterilized as a unit so as to insure a surgically-sterile condition of the drape sheet therein, said drape sheet being unharmed by said sterilization and being ready for removal and immediate use by a surgeon whenever desired, without further sterilization being required.

2. An article according to claim 1 characterized by the feature that the adhesive strip area surrounds an aperture in the film sheet, the size of the aperture being relatively small compared to the area of the sheet.

3. An article according to claim 1 characterized by the feature that the drape sheet is folded upon itself and is enclosed within an inner wrapper contained in an outer sealed protective envelope.

4. An article according to claim 1 characterized by the feature that the drape sheet is transparent or translucent and the film is composed of a synthetic organic polymer.

5. An article according to claim 1 characterized by the feature that the pressure-sensitive adhesive is of the acrylate type.

6. An article according to claim 1 characterized by the feature that the pressure-sensitive adhesive includes a bactericide.

7. A sterile-packaged adhesive-coated drape sheet for surgical and like uses substantially as herein described with reference to the embodiments shown in the accompanying drawings.

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Chartered Patent Agents.
Agents for the Applicants.

Leamington Spa: Printed for Her Majesty's Stationery Office, by the Courier Press.—1953.
Published at The Patent Office, 25, Southampton Buildings, London, W.C.2, from which copies may be obtained.

692,578 COMPLETE SPECIFICATION

3 SHEETS

This drawing is a reproduction of the Original on a reduced scale.

SHEET 1

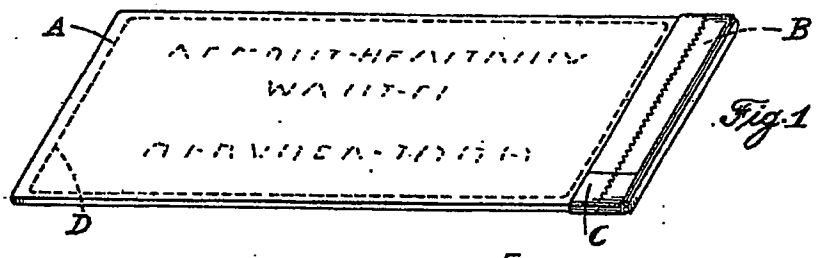

Fig. 1

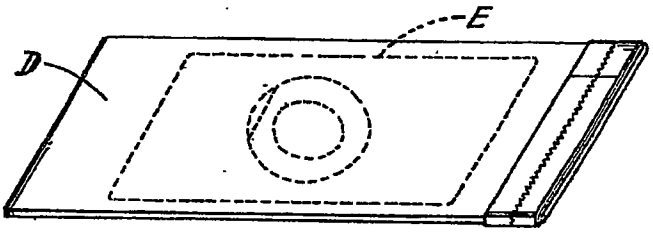

Fig. 2

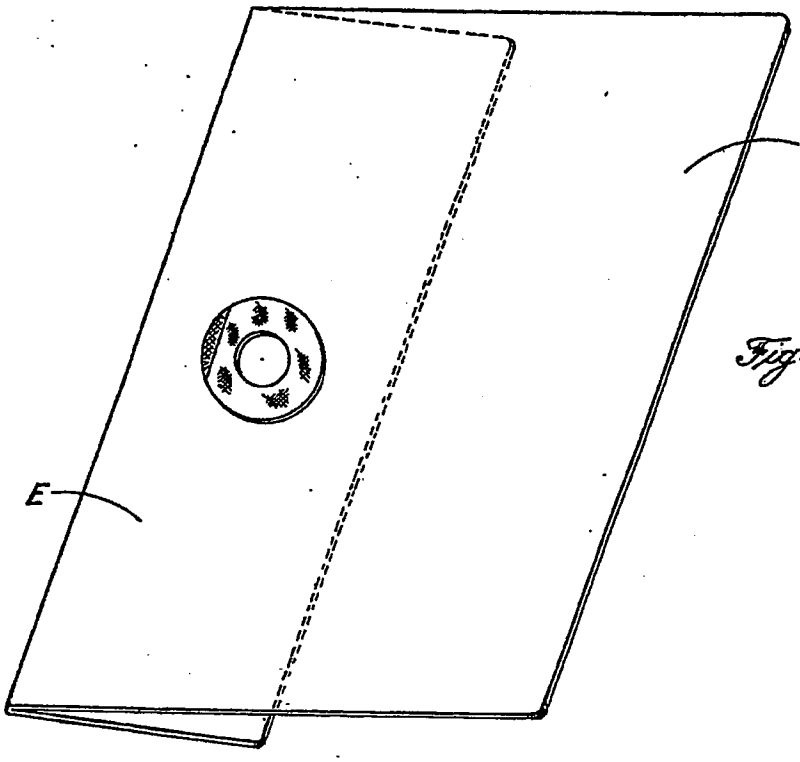

Fig. 3

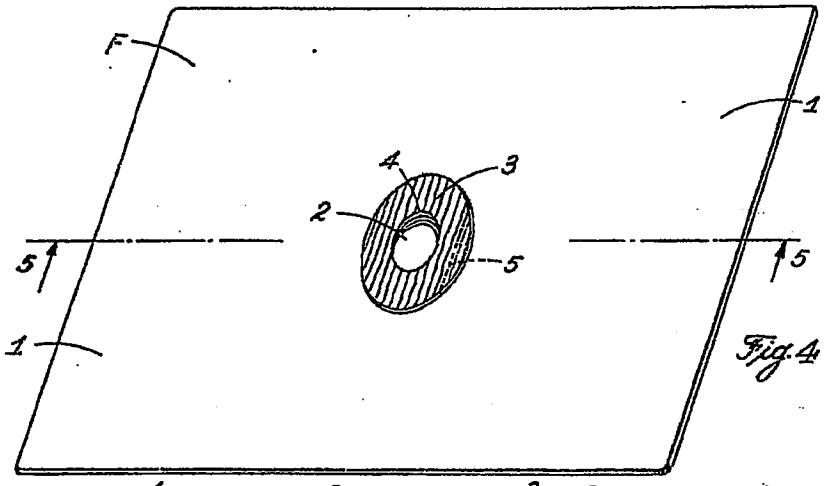

Fig. 4

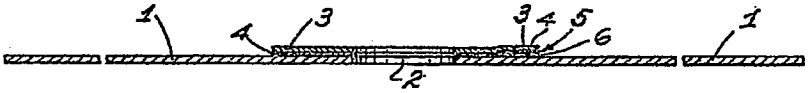

Fig. 5

Fig. 6

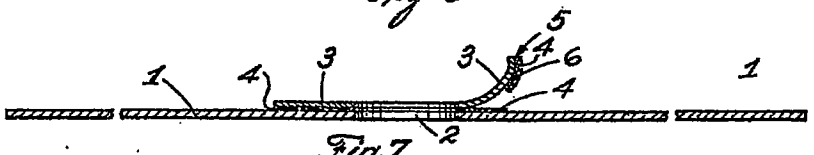

Fig. 7

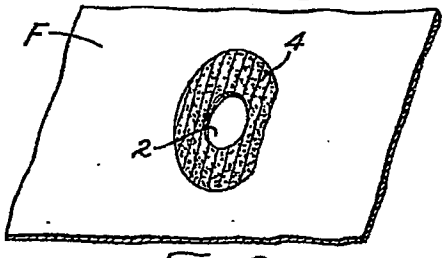

Fig. 8

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SHEETS 2 & 3

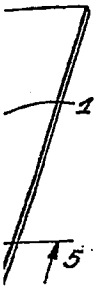

Fig. 4

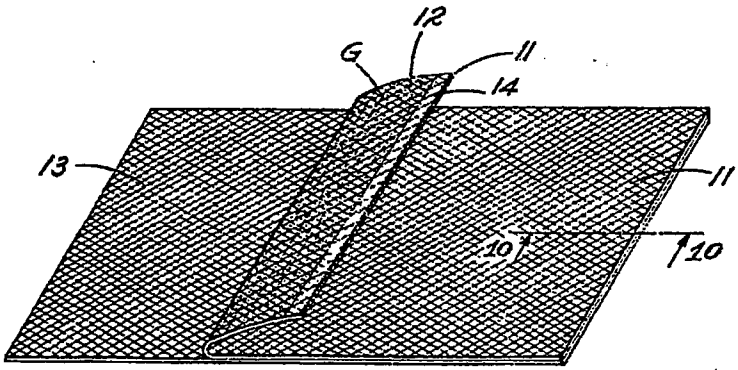

Fig. 9

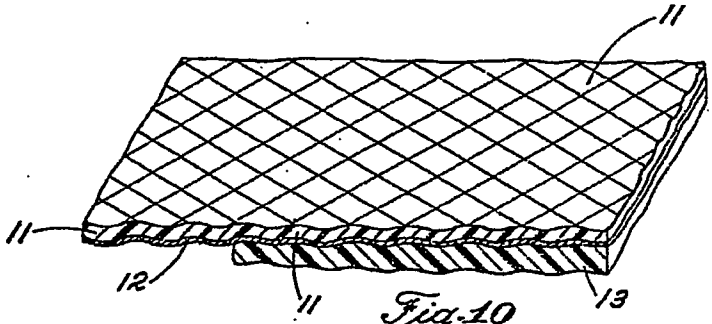

Fig. 10

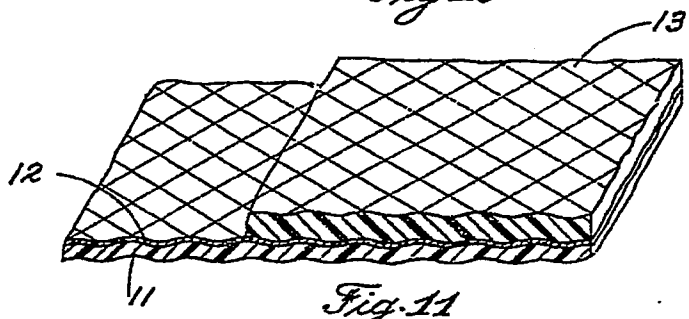

Fig. 11

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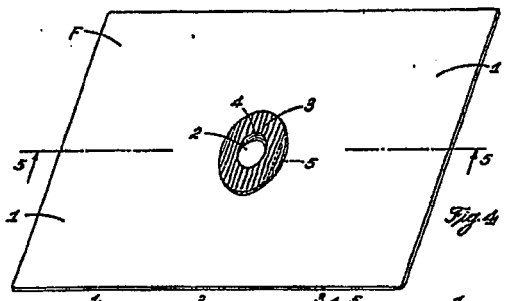

Fig.4

Fig.5

Fig.6

Fig.7

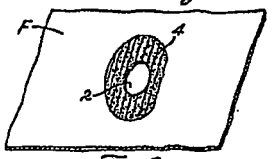

Fig.8

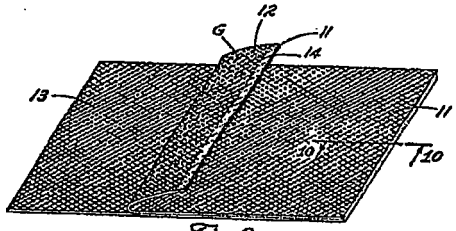

Fig.9

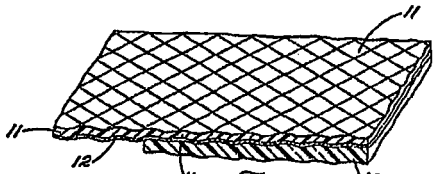

Fig.10

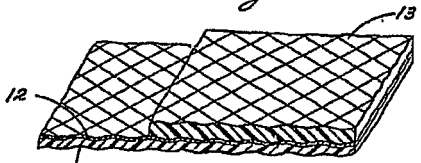

Fig.11

(12) UK Patent Application (19) GB (11) 2 197 789 (13) A

(43) Application published 2 Jun 1988

(21) Application No 8726318

(22) Date of filing 10 Nov 1987

(30) Priority data
(31) 8628564 (32) 28 Nov 1986 (33) GB

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(51) INT CL⁴
A01N 25/00 A61L 2/18 A61M 1/00

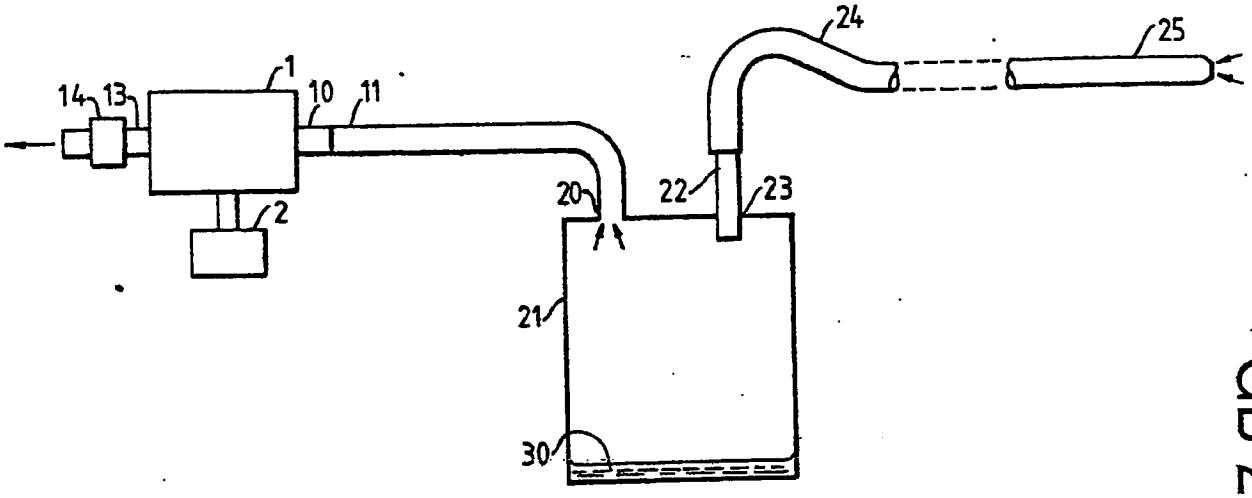
(52) Domestic classification (Edition J):
A5E 311 312 314 317 T
U1S 1052 1307 1427 A5E

(56) Documents cited
GB 1542520 GB 1504587 US 4089977

(58) Field of search
A5E
Selected US specifications from IPC sub-classes
A01N A61L

(54) Anti-foaming disinfectants used in surgical suction apparatus

(57) Medico-surgical suction apparatus has a collection vessel (21) into which is aspirated body fluid. The collection vessel contain an anti-foaming agent (30) that has disinfecting properties sufficient to disinfect its full contents. A typical anti-foaming agent comprises 59.99% of formaldehyde in a 38% concentration solution, 29.89% of gluteraldehyde in a 50% concentration solution, 9.295% of a silicone emulsion defoamer, 0.75% of a thickener and 0.075% of a colouring agent. This composition is effective at concentrations as low as 1.0% of the collection vessel volume.



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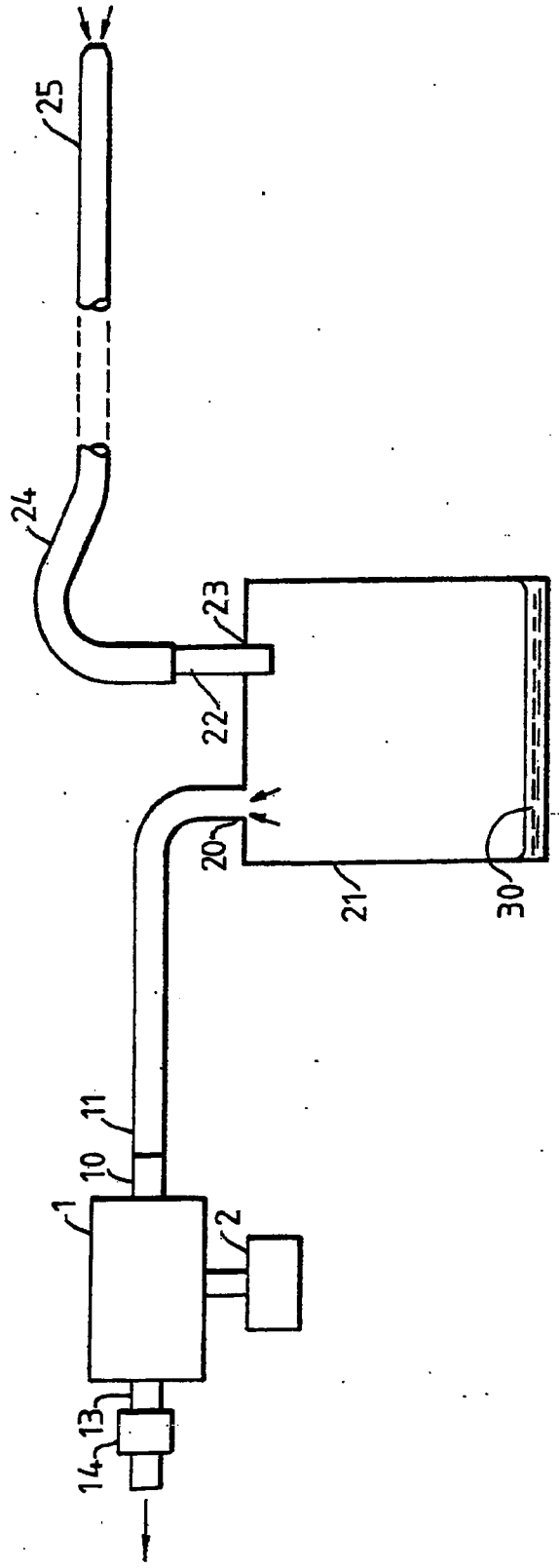
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ANTI-FOAMING AGENTS, COLLECTION VESSELS AND SUCTION APPARATUS

This invention relates to anti-foaming agents and to collection vessels, and suction apparatus employing anti-foaming agents.

The invention is more particularly concerned with anti-foaming agents for use in medical or surgical suction apparatus.

Suction apparatus used in medicine or surgery commonly employs a vacuum pump having its inlet connected to a collection vessel which receives fluid from a suction catheter. The vacuum pump creates a reduced pressure in the collection vessel which sucks fluid along the catheter.

Such apparatus is used to remove blood, other body fluids and tissue debris from surgical wound sites and body cavities. As the fluid enters the collection vessel there may be a tendency for it to foam. Unless measures are taken to reduce the foam, it will rapidly fill the collection vessel and can be sucked into the vacuum pump leading to damage and to spread of infection. In addition, it can give a false indication of the volume of fluid collected; this is a disadvantage since knowledge of the fluid volume is clinically important.

Foaming within the collection vessel can be reduced by adding a known anti-foaming liquid, such as a silicone emulsion, to the collection vessel prior to use.

After use, the fluid in the collection vessel may contain high quantities

of pathogenic bacteria and viruses. Current methods of handing full collection vessels is hazardous and disposal of their contents carries a high risk of cross infection.

It is one object of the present invention to provide an anti-foaming agent that can be used to reduce this risk of cross-infection.

According to one aspect of the present invention there is provided an anti-foaming agent for use in the collection vessel of medico-surgical suction apparatus, wherein the agent has disinfecting properties sufficient to disinfect the full contents of the collection vessel.

The agent may be effective in quantities less than 7.5% of the volume of the collection vessel and is preferably effective in quantities about 1% of the volume. The agent may include formaldehyde and gluteraldehyde and preferably includes substantailly 60% of a substantially 38% concentration formaldehyde solution and substantially 30% of a substantially 50% concentration gluteraldehyde solution. The agent may include substantially 9% of an anti-foaming composition which may be a silicone emulsion defoamer. The agent preferably additionally includes a thickener and a colouring agent. The anti-foaming agent may comprise substantially 59.99% of formaldehyde in a 38% concentration solution, 29.89% of gluteraldehyde in a 50% concentration solution, 9.295% of a silicone emulsion defoamer, 0.75% of a thickener and 0.075% of a colouring agent.

Alternatively, the agent may contain a biocide containing a mixture of di(2-hydroxy ethoxy methane) in equilibrium with its precursors:

$C_5H_{12}O_4 = C_3H_8O_3$. The agent may contain substantially 83% by weight of the biocide.

According to another aspect of the present invention there is provided a collection vessel for containing fluid aspirated from a surgical wound site or body cavity, the vessel containing an anti-foaming agent in a small quantity compared with the volume of the vessel, the agent having disinfecting properties sufficient to disinfect the full contents of the collection vessel.

The agent may be present in a quantity less than 7.5% of the volume of the collection vessel and is preferably present in a quantity about 1% of the volume. The agent may include formaldehyde and gluteraldehyde and preferably includes substantially 60% of a substantially 38% concentration formaldehyde solution and substantially 30% of a substantially 50% concentration gluteraldehyde solution. The agent may include substantially 9% of an anti-foaming composition which may be a silicone emulsion defoamer. The agent preferably additionally includes a thickener. A part at least of the vessel is preferably transparent, the agent including a colouring agent. The agent may comprise substantially 59.99% of formaldehyde in a 38% concentration solution, 29.89% of gluteraldehyde in a 50% concentration solution, 9.295% of a silicone emulsion defoamer, 0.75% of a thickener and 0.075% of a colouring agent, a part at least of the vessel being transparent.

Alternatively, the agent may contain a biocide containing a mixture of di(2-hydroxy ethoxy methane) in equilibrium with its precursors: $C_5H_{12}O_4 = C_3H_8O_3$. The agent may contain substantially 83% by weight of the biocide.

It is another object to provide medico-surgical suction apparatus that can be used to reduce the dangers of handling collection vessels.

According to a further aspect of the present invention there is provided medico-surgical suction apparatus including a collection vessel according to the above other aspect of the present invention, means for applying a vacuum to the collection vessel, and a suction catheter connected with the collection vessel such that the vacuum causes fluid to be aspirated from the surgical wound site or body cavity via the suction catheter into the collection vessel and to be disinfected in the collection vessel on contact with the anti-foaming agent.

Medico-surgical suction apparatus including a collection vessel containing an anti-foaming agent, in accordance with the present invention, will now be described, by way of example, with reference to the accompanying drawing which shows the apparatus schematically.

The suction apparatus includes a vacuum pump 1 that is driven by an electric motor 2. The pump has an inlet 10 that is connected via a pipe 11 to an opening 20 at the top of a transparent collection vessel or bottle 21. An inlet tube 22 extends vertically through a second opening 23 into the collection bottle 21, the upper end being connected by flexible tubing 24 to a suction catheter 25. The collection bottle 21 is sealed, apart from the openings 20 and 23 communicating respectively with the pump 1 and the tubing 24. The outlet 13 of the pump 1 vents to atmosphere via a bacterial filter 14. The suction apparatus as so far described is entirely conventional.

The collection bottle 21 contains a small volume of a novel anti-foaming agent 30. The quantity of anti-foaming agent 30 needed will depend on the volume of collection bottle; typically, for a 2 litre bottle about 20 ml of the anti-foaming agent is required, that is, about 1.0%.

The anti-foaming agent is in liquid form comprising: 59.99% of formaldehyde in a 38% concentration solution; 29.89% of gluteraldehyde in a 50% concentration solution; 9.295% of a silicone emulsion anti-foaming composition such as Silcolapse 5000 made by ICI; 0.75% of a thickener such as Viscalex AT66; and 0.075% of a colouring agent such as a 0.1% solution of Loeffler's Methylene Blue.

This combination of formaldehyde and gluteraldehyde has been found to be particularly effective as a disinfectant, destroying the majority of micro-organisms, including bacteria and viruses, within a period of 1 minute when the anti-foaming agent is present at concentrations as low as 1.0% in the collection vessel. This disinfectant has also been found not to have any significant deleterious effect on the properties of the anti-foaming

composition or to be affected adversely by the anti-foaming composition.

The colouring agent serves to make the anti-foaming agent more identifiable in the collection bottle prior to aspiration which is a useful feature when the anti-foaming agent is only present in small quantities.

An alternative anti-foaming agent can be made of about 83% by weight of Phylatol, a biocide made by BDH Chemicals Limited and containing a mixture of di (2-hydroxy ethoxy methane) in equilibrium with its precursors: $C_5H_{12}O_4 = C_3H_8O_3$. The remainder of the anti-foaming agent comprises a silicone emulsion defoamer such as Silcolapse 5000 made by ICI, and a small quantity of a stabiliser, such as sodium carboxymethyl cellulose. The purpose of the stabiliser is to increase the viscosity of the blend so as to improve its stability. A coloured dye may also be added. This alternative anti-foaming agent has been found to be effective but to require greater quantities, typically 30ml would be required in a 2 litre bottle, that is 1.5%.

The criteria for selection of an anti-foaming agent with disinfecting properties are that it must be effective in small concentrations, typically less than about 7.5% of the collection vessel full volume. If an anti-foaming agent has to be used in large concentrations, this reduces the volume available for aspirated fluid thereby making it necessary to change the collection bottle more frequently or risk overflow. The anti-foaming agent must also effectively disinfect in the presence of blood. The term 'disinfection' is defined in BS5283:1976.

An investigation of various disinfectants failed to reveal any other disinfectant that meets these criteria and remains compatible with the

defoaming agent. It will be appreciated, however, that the present invention is not restricted to the disinfectants referred to above but that other compositions capable of meeting the criteria may be used.

In use, the pump 1 creates a reduced pressure within the collection bottle 21, any fluid or tissue debris in the region of the patient end of the suction catheter 25 being sucked along the inlet tube 22 and into the collection bottle. As it enters the collection bottle 21, the aspirated fluid will mix with the anti-foaming agent 30 thereby dispersing it within the contents of the collection bottle. The majority of micro-organisms in the aspirated fluid are killed by the disinfecting properties of the agent 30, whilst foaming is inhibited by its anti-foaming properties. At the end of the procedure, the collection bottle 21 can be removed and the contents disposed of with a significantly reduced risk of cross-infection.

CLAIMS

1. An anti-foaming agent for use in the collection vessel of medico-surgical suction apparatus, wherein the agent has disinfecting properties sufficient to disinfect the full contents of the collection vessel.

2. An anti-foaming agent according to Claim 1, wherein the agent is effective in quantities less than 7.5% of the volume of the collection vessel.

3. An anti-foaming agent according to Claim 2, wherein the agent is effective in quantities about 1% of the volume of the collection vessel.

4. An anti-foaming agent according to any one of the preceding claims, wherein the agent includes formaldehyde and gluteraldehyde.

5. An anti-foaming agent according to any one of the preceding claims, wherein the agent includes substantially 60% of a substantially 38% concentration formaldehyde solution.

6. An anti-foaming agent according to any one of the preceding claims, wherein the agent includes substantally 30% of a substantially 50% concentration gluteraldehyde solution.

7. An anti-foaming agent according to any one of the preceding

claims, wherein the agent includes substantially 9% of an anti-foaming composition.

8. An anti-foaming agent according to Claim 7, wherein the anti-foaming composition is a silicone emulsion defoamer.

9. An anti-foaming agent according to any one of the preceding claims, wherein the agent additionally includes a thickener.

10. An anti-foaming agent according to any one of the preceding claims, wherein the agent includes a colouring agent.

11. An anti-foaming agent according to any one of the preceding claims comprising substantially 59.99% of formaldehyde in a 38% concentration solution, 29.89% of gluteraldehyde in a 50% concentration solution, 9.295% of a silicone emulsion defoamer, 0.75% of a thickener and 0.075% of a colouring agent.

12. An anti-foaming agent according to Claim 1 or 2, wherein the agent contains a biocide containing a mixture of di(2-hydroxy ethoxy methane) in equilibrium with its precursors:

$C_5H_{12}O_4 = C_3H_8O_3$.

13. Anti-foaming agent according to Claim 12, wherein the agent contains substantially 83% by weight of the said biocide.

14. An anti-foaming agent substantially as hereinbefore described with reference to the accompanying drawing.

15. A collection vessel for containing fluid aspirated from a surgical wound site or body cavity, wherein the vessel contains an anti-foaming agent in a small quantity compared with the volume of the vessel, and wherein the agent has disinfecting properties sufficient to disinfect the full contents of the collection vessel.

16. A collection vessel according to Claim 15, wherein the agent is present in a quantity less than 7.5% of the volume of the collection vessel.

17. A collection vessel according to Claim 16, wherein the agent is present in a quantity about 1% of the volume of the collection vessel.

18. A collection vessel according to any one of Claims 15 to 17, wherein the agent includes formaldehyde and gluteralehyde.

19. A collection vessel according to any one of Claims 15 to 18, wherein the agent includes substantially 60% of a substantially 38% concentration formaldehyde solution.

20. A collection vessel according to any one of Claims 15 to 19, wherein the agent includes substantially 30% of a substantially 50% concentration gluteraldehyde solution.

21. A collection vessel according to any one of Claims 15 to 20, wherein the agent includes substantially 9% of an anti-foaming composition.

22. A collection vessel according to Claim 21, wherein the anti-foaming composition is a silicone emulsion defoamer.

23. A collection vessel according to any one of Claims 15 to 22, wherein the agent additionally includes a thickener.

24. A collection vessel according to any one of Claims 15 to 23, wherein a part at least of the vessel is transparent, and wherein the agent includes a colouring agent.

25. A collection vessel according to any one of Claims 15 to 24, wherein the agent comprises substantially 59.99% of formaldehyde in a 38% concentration solution, 29.89% of gluteraldehyde in a 50% concentration solution, 9.295% of a silicone emulsion defoamer, 0.75% of a thickener and 0.075% of a colouring agent, and wherein a part at least of the vessel is transparent.

26. A collection vessel according to Claim 15 or 16, wherein the agent contains a biocide containing a mixture of di(2-hydroxy ethoxy methane) in equilibrium with its precursors:
$C_5H_{12}O_4 = C_3H_8O_3$.

27. A collection vessel according to Claim 26, wherein the agent contains substantially 83% by weight of the said biocide.

28. A collection vessel substantially as hereinbefore described with reference to the accompanying drawing.

29. Medico-surgical suction apparatus including a collection vessel according to any one of claims 15 to 28, means for applying a vacuum to the collection vessel, and a suction catheter connected with the collection vessel such that the vacuum causes fluid to be aspirated from the surgical wound site or body cavity via the suction catheter into the collection vessel and to be disinfected in the collection vessel on contact with the anti-foaming agent.

30. Medico-surgical suction apparatus substantially as hereinbefore described with reference to the accompanying drawing.

31. Any novel feature or combination of features as hereinbefore described.

(12) UK Patent Application (19) GB (11) 2 220 357 (13) A

(43) Date of A publication 10.01.1990

(21) Application No 8911950.7

(22) Date of filing 24.05.1989

(30) Priority data
(31) 8812803 (32) 28.05.1988 (33) GB

(51) INT CL⁴
A61M 1/00

(52) UK CL (Edition J)
A5R RCE

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(58) Field of search
UK CL (Edition J) A5R RCE
INT CL⁴ A61M

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(54) Medico-surgical containers

(57) A medico-surgical suction container has an inlet 10 connected to a suction catheter 11 and an outlet 20 connected to a pump 21 capable of reducing pressure in the container to at least 500 mm Hg below atmosphere. Within the container, in line with the outlet 20, is a housing 44 containing a filter 41 having a layer of a PTFE membrane on a support screen and a layer of a glass microfibre laminated to a polymer monofilament. The filter 41 allows passage of gas from the container but prevents passage of bacteria and liquid. A tube 43 projects down from the filter housing 44 into the container, the lower end of which defines the maximum filling level, thereby preventing overfilling of the container. The inlet 10 and outlet 20 are formed in recesses 13 and 23 which can be sealed by plugs 14 and 24 attached to the container by flexible webs 15 and 25. The plugs 14 and 24, when inserted, form a smooth surface of the recesses, thereby preventing subsequent removal. An expansion chamber 30 has a convex base plate 31 beneath the inlet 10 so that liquid flows outwardly and down the edge of the plate between a gap 32 with the container and through slots 33 at the edge of the plate.

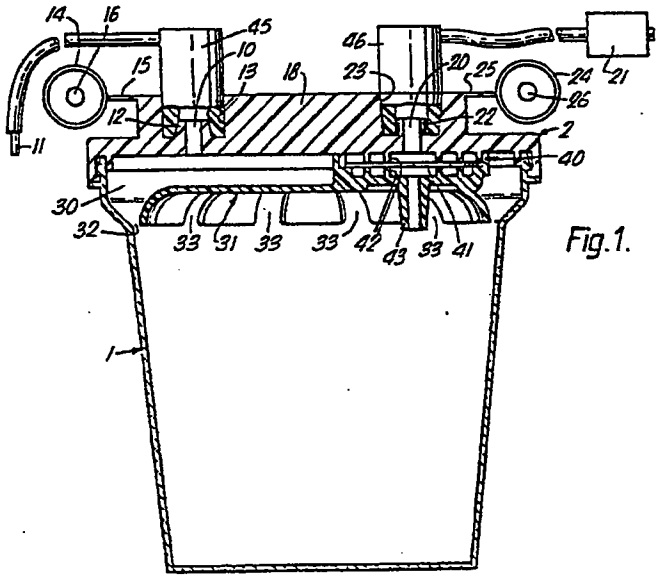

Fig.1.

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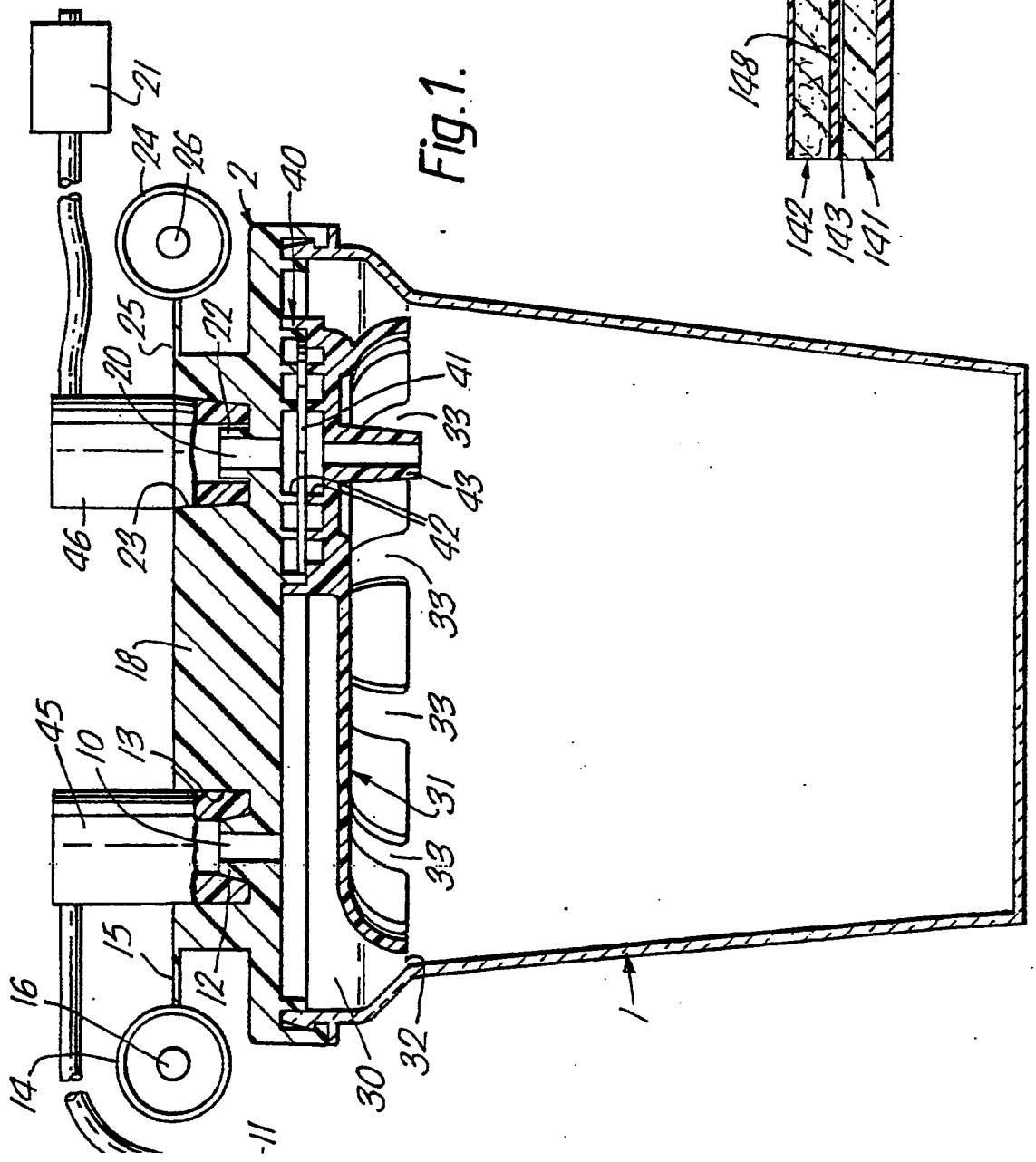


Fig.1.

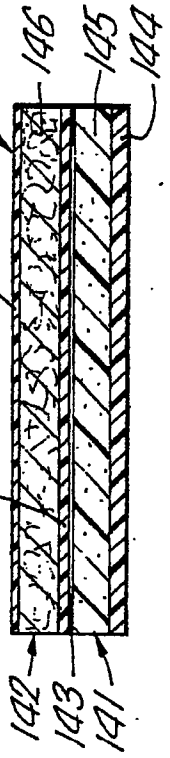


Fig.4.

Fig.2.

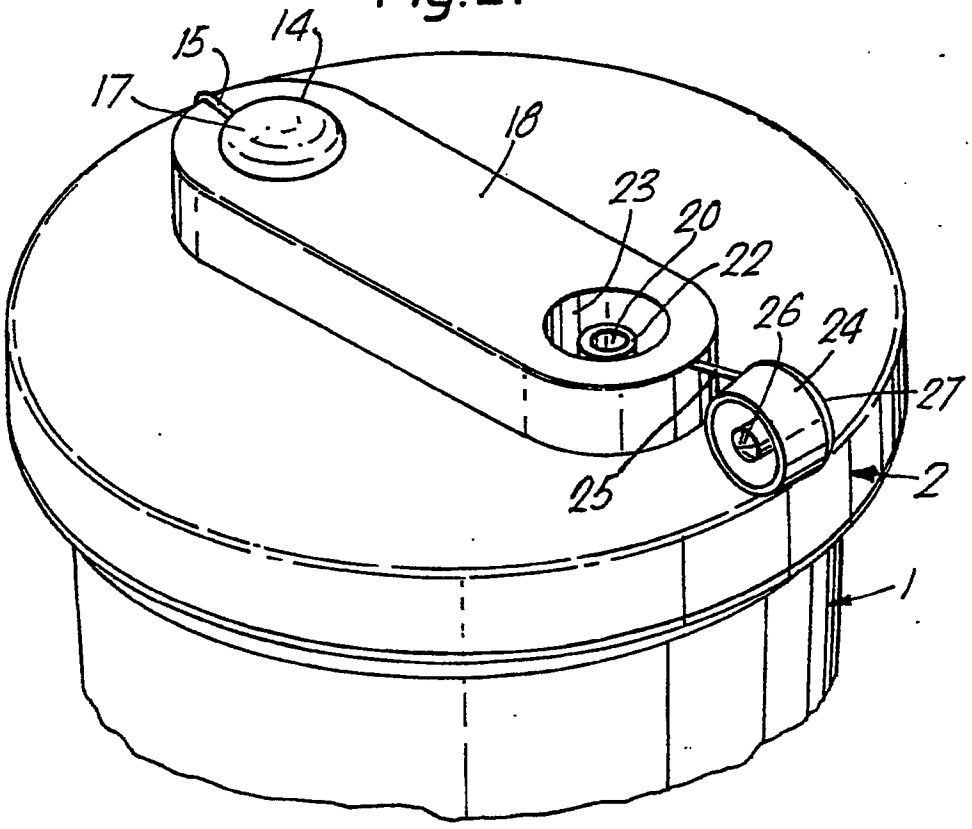
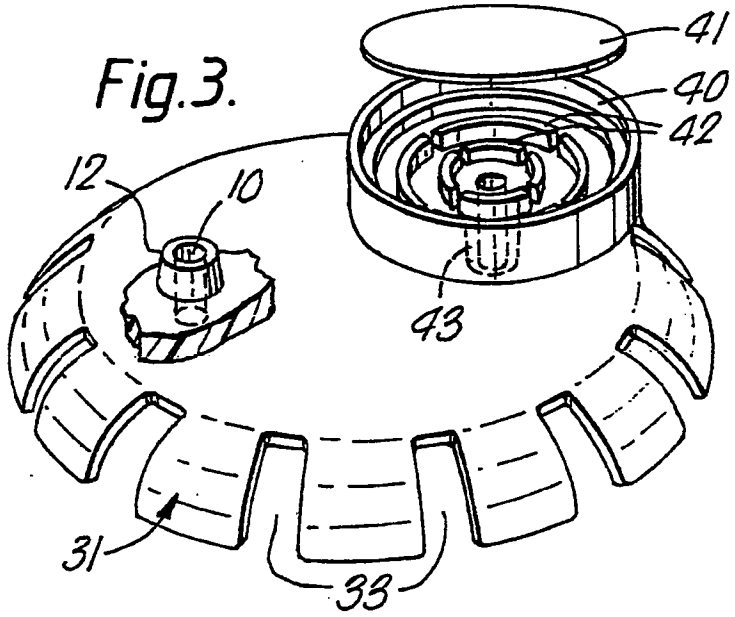


Fig.3.



MEDICO-SURGICAL CONTAINERS AND SUCTION SYSTEMS

This invention relates to medico-surgical containers and suction systems.

The invention is more particularly concerned with containers for collecting liquid and other debris removed from a surgical site by suction in a suction system.

Suction applied by a vacuum pump is used to remove blood, irrigation liquid, tissue debris and the like during surgery. The suction system commonly comprises a suction catheter, a vacuum pump and a collection container. The collection container has two openings one of which is connected to the suction catheter and the other of which is connected to the vacuum pump. The reduced pressure produced by the vacuum pump is communicated with the suction catheter via the container so that material in the surgical site can be sucked along the catheter and collected in the container.

Such collection containers usually have a float-actuated ball valve in the outlet connected to the vacuum pump, the ball valve closing when the liquid in the container rises above a preset level, so as to prevent the liquid being sucked into the vacuum pump. A bacterial filter is often connected between the container and the pump to prevent any airborne or aerosol-borne bacteria being dispersed to the atmosphere.

Because the contents of the collection container after use are often contaminated, their safe disposal presents problems.

It is an object of the present invention to provide an improved medico-surgical container.

According to one aspect of the present invention there is provided a medico-surgical container having an inlet for connection to a suction catheter, an outlet for connection to a vacuum pump, and a filter member located in the container in line with the outlet, the filter member allowing passage of gas from the container to the outlet but preventing passage of bacteria and of liquid such that overfilling of the container is prevented by the filter member.

In this way, the need for a separate float valve and bacterial filter is obviated.

The filter member is preferably contained within a housing having a tube projecting downwardly into the container, the lower end of the tube defining the maximum filling level of the container. The filter member may include a layer comprising a PTFE membrane on a support screen and may include a layer including a glass microfibre laminated to a polymer monofilament.

The container preferably includes plug means for sealing the inlet and outlet after use. The inlet and outlet may be formed in respective recesses, the plug means being shaped such that when inserted they form a smooth surface of the recess making subsequent removal of the plug difficult. The plug means may be each attached to the container by means of a flexible web.

The container preferably includes an expansion chamber located beneath the inlet. The expansion chamber may have a base plate of convex shape arranged such that the liquid from the inlet flows outwardly and down the edge of the plate. The outlet from the expansion chamber is preferably at the edge of the base plate and may include slots formed at the edge of the base plate.

According to another aspect of the present invention there is provided a medico-surgical suction system including a container according to the above one aspect of the invention, a suction catheter connected in communication with the inlet and a vacuum pump connected in communication with the outlet.

The pump is preferably capable of delivering a pressure of at least 500 mm Hg below atmosphere in the container.

A suction system including a suction container in accordance with the present invention will now be described, by way of example, with reference to the accompanying drawings, in which:

Figure 1 is a sectional side elevation view of the container;

Figure 2 is a perspective view of the top of the container;

Figure 3 is a perspective view of the interior of the top of the container; and

Figure 4 is a sectional elevation through the filter member of the container.

With reference first to Figures 1 and 2, the surgical suction system includes a container comprising a cylindrical, transparent jar 1 of a plastics or glass and a top closure 2 that is irremovably sealed to the jar. An inlet 10 and outlet 20 are provided in the top closure 2 that are connected respectively to a suction catheter 11 and a vacuum pump 21 capable of delivering a vacuum of at least 500 mm Hg below atmosphere in the jar 1.

The inlet 10 and outlet 20 both have a vertical spigot 12 and 22 located within respective cylindrical recesses 13 and 23 formed in a handle 18 that extends across the top of the closure 2. The inlet spigot 12 has a tapered outer surface which mates with a female connector 45 that is connected to the suction catheter 11. The outlet recess 23 is tapered outwardly towards its upper end to receive therein, as a mating fit, a male connector 46 that is connected to the vacuum pump 21. The connectors 45 and 46 are differently shaped and the recesses 13 and 23 are of different diameters so that it is not possible to fit the connectors into the wrong recesses. At opposite ends of the handle 18, plugs 14 and 24 are attached by means of short flexible webs 15 and 25, one of the plugs 14 being shown inserted in Figure 2. One side of each plug 14 and 24 is hollow and formed with a central nose 16 and 26, the external diameter of each plug being such that it is a close, push fit within the recess 13 and 23 with the nose

being a close sealing fit within the respective spigot 12 and 22. The other side of each plug 14 and 24 has a shallow convex surface 17 and 27 respectively. The plugs 14 and 24 can be inserted into their adjacent recess 10 or 20 by bending and twisting their web 15 and 25 so that the convex surface 17 or 27 forms a smooth, shallow projection from the handle which cannot be gripped easily. This prevents the plugs being pulled out readily once inserted.

The inlet 10 opens into an expansion chamber 30 formed in the top closure 2 and seen most clearly in Figure 3. The chamber 30 has a base plate 31 of convex shape which underlies the inlet 10 so that liquid from the inlet flows outwardly and down the edge of the plate. The diameter of the plate 31 is slightly less than that of the jar 1 so that an annular gap is formed around the outer edge of the plate, between the inner surface of the jar, which provides an outlet from the chamber 30 offset laterally from its inlet 10. Radial slots 33 are spaced around the edge of the plate 31 to provide additional liquid flow paths into the jar. The purposes of the expansion chamber 30 is to reduce turbulence and splashing inside the jar 1 by providing an indirect and smooth flow of liquid from the expansion chamber into the jar.

The spigot 22 of the vacuum outlet 20 opens into a filter assembly 40 in the top closure 2. The filter assembly 40 has a housing 44 containing a hydrophobic filter element 41 of the kind sold by Arbor Technologies under the trade mark CONTAIN and the code number 85005. The element 41 is shown in more detail in Figure 4 and is a membrane made up of two layers 141 and 142 bonded together around their edge 143. The layer 141 facing the inside of the jar 1 comprises a PTFE membrane 144 laminated with a polypropylene support screen 145, the PTFE membrane facing outwardly. This layer is tested to withstand water breakthrough at at least 10 psi. The layer 142 facing the pump 21 is a glass microfibre 146 which is laminated on both sides with polypropylene monofilament 147 and 148 that is treated to render it hydrophobic. The element 41 is retention rated at a particle size of 0.3 micron and can withstand pressure across it of 700 mm Hg. Although different forms of filter element may be effective at removing bacteria at low pressure, at the relatively high pressures encountered in surgical suction systems, a membrane type of element, such as of the kind described, is most effective. The element 41 is supported on both sides by ribs 42 formed internally of the housing 44. On its lower side, the filter assembly 40 communicates with a short vertical vent tube 43 that projects downwardly of the housing 44 into the jar 1 by a short distance, the lower end of the vent tube defining the maximum filling volume of the jar. The element 41 thereby communicates with the jar 1 without the interpositon

of any separate valve or overflow prevention device.

When the pump 21 is turned on, it draws air out of the container through the filter assembly 40 which acts as a bacterial filter to prevent contamination of the pump or atmosphere. The reduced pressure inside the container causes suction to be applied to the suction inlet 10 and hence to the suction catheter 11. This in turn causes any liquid or small debris in the region of the operative tip of the catheter 11 to be sucked along the catheter, through the inlet 10 and the expansion chamber 30 into the container until the level of contents in the jar 1 reaches the lower end of the vent tube 43. When this happens, liquid is drawn up the tube 43 into the filter assembly 40. Although the filter element 41 allows passage of gas, it prevents the passage of liquid, so that the contents of the container are prevented from reaching the vacuum outlet 20. Because further gas flow to the vacuum pump 21 is prevented, suction ceases at the catheter 11, signalling to the user that the container is full. The user then turns off the pump and disconnects the inlet 10 and outlet 20 from their connections, thereby allowing liquid in the filter assembly 40 and tube 43 to flow back down into the jar 1. The plugs 14 and 24 are then pushed into the respective recesses 13 and 23 to seal the jar 1 closed.

The hydrophobic filter serves the dual function of preventing overfilling and of removing bacteria from gas vented from the container. It avoids the need to provide a separate bacterial filter, thereby simplifying the setting up of the suction system. There is a risk, where a separate bacterial filter is used, that replacement of the filter will be overlooked and that a filter may be left in the system long enough to become damaged. In the present arrangement, because the filter is disposed of every time the collection jar is full, there is less risk of contamination caused by use of a damaged filter. The use of a membrane type filter element enables effective bacterial filtering at the relatively high pressure differentials of about 500 mm Hg encountered in surgical suction systems.

CLAIMS

1. A medico-surgical container having an inlet for connection to a suction catheter, an outlet for connection to a vacuum pump, and a filter member located in said container in line with the outlet, the filter member allowing passage of gas from the container to the outlet but preventing passage of bacteria and of liquid such that overfilling of the container is prevented by said filter member.

2. A container according to Claim 1, wherein the filter member is contained within a housing having a tube projecting downwardly into the container, the lower end of the tube defining the maximum filling level of the container.

3. A container according to Claim 1 or 2, wherein the filter member includes a layer comprising a PTFE membrane on a support screen.

4. A container according to any one of the preceding claims, wherein the filter member includes a layer including a glass microfibre laminated to a polymer monofilament.

5. A container according to one of the preceding claims including plug means for sealing the inlet and outlet after use.

6. A container according to Claim 5, wherein the inlet and outlet are formed in respective recesses, and wherein the plug means are shaped such that when inserted they form a smooth surface of the recess making subsequent removal of the plug means difficult.

7. A container according to Claim 5 or 6, wherein the plug means are each attached to the container by means of a flexible web.

8. A container according to any one of the preceding claims, wherein the container includes an expansion chamber located beneath the inlet.

9. A container according to Claim 8, wherein the expansion chamber has a base plate of convex shape arranged such that liquid from the inlet flows outwardly and down the edge of the plate.

10. A container according to Claim 9, wherein the outlet from the expansion chamber is at the edge of the base plate.

11. A container according to Claim 10, wherein the outlet from the expansion chamber includes slots formed at the edge of the base plate.

12. A container substantially as hereinbefore described with reference to the accompanying drawings.

13. A medico-surgical suction system including a container according to any one of the preceding claims, a suction catheter connected in communication with the inlet and a vacuum pump connected in communication with the outlet.

14. A medico-surgical suction system according to Claim 13, wherein the pump is capable of delivering a pressure of at least 500 mm Hg below atmosphere in the container.

15. A medico-surgical suction system substantially as hereinbefore described with reference to the accompanying drawings.

16. Any novel feature or combination of features as hereinbefore described.

(12) UK Patent Application (19) GB (11) 2 235 877 (13) A

(43) Date of A publication 20.03.1991

(21) Application No 8921084.3

(22) Date of filing 18.09.1989

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(51) INT CL[5]
A61M 1/00

(52) UK CL (Edition K)
A5R RCE RCW

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(58) Field of search
UK CL (Edition J) A5R RCE RCW
INT CL[4] A61M

(54) Closed wound suction apparatus

(57) A closed wound suction apparatus comprises a housing, within which there is accommodated a microprocessor controlled battery powered suction pump, and a detachable drainage container arranged to be evacuated by the suction pump so as to apply a suction pressure to a drainage tube embedded in a closed postoperative wound. The suction pressure can be set by the surgeon and is monitored by a pressure sensor which reports to the pump control to determine operation of the pump in accordance with a predetermined set routine. Other controls that can be provided can monitor the volume of exudate in the container and/or the flow rate of exudate into the container. The container is preferably disposable and has self-sealing ports for connection to the vacuum pump and to the drainage tube.

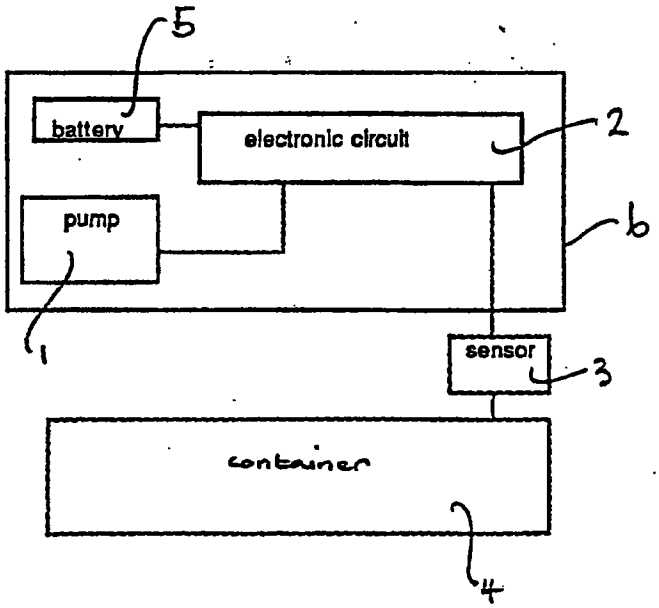

FIG 3

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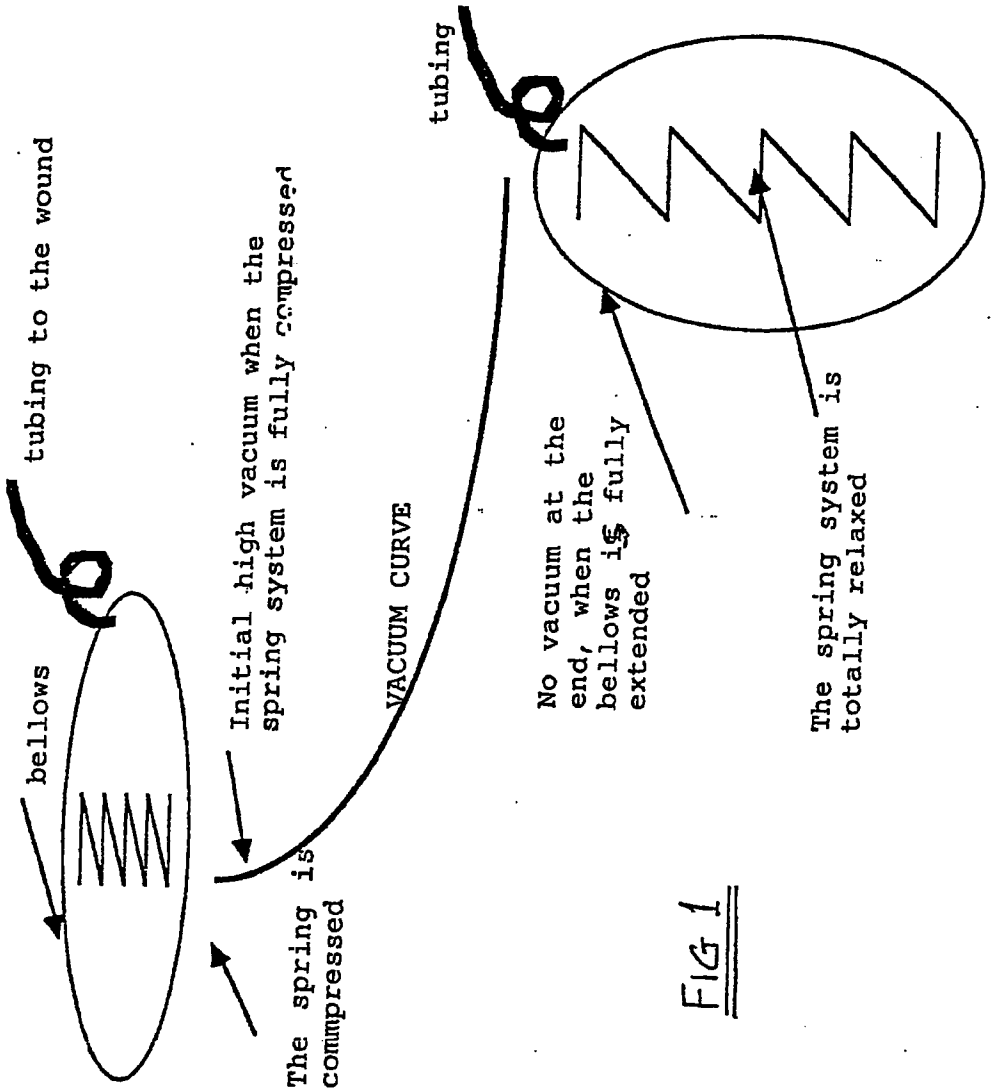

tubing to the wound
bellows
Initial high vacuum when the spring system is fully compressed
VACUUM CURVE
tubing
The spring is compressed
No vacuum at the end, when the bellows is fully extended
The spring system is totally relaxed

FIG 1

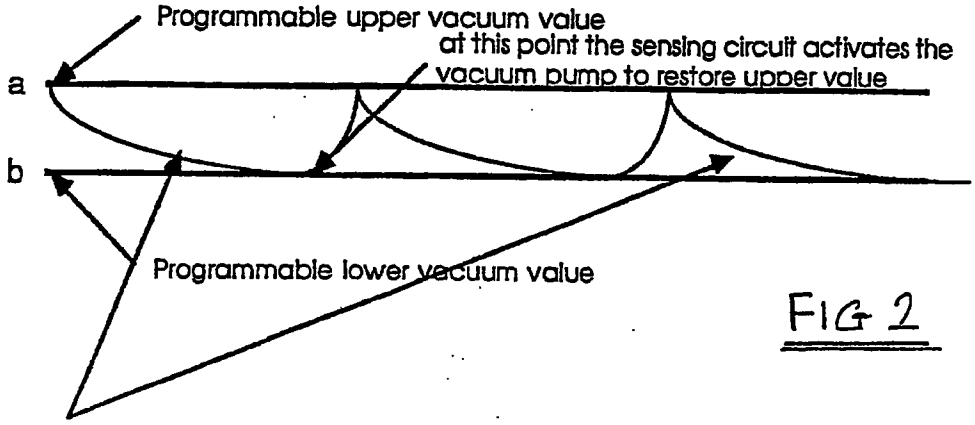


FIG 2

Vacuum curves behaviour, within a pre-programmed working window (a-b)

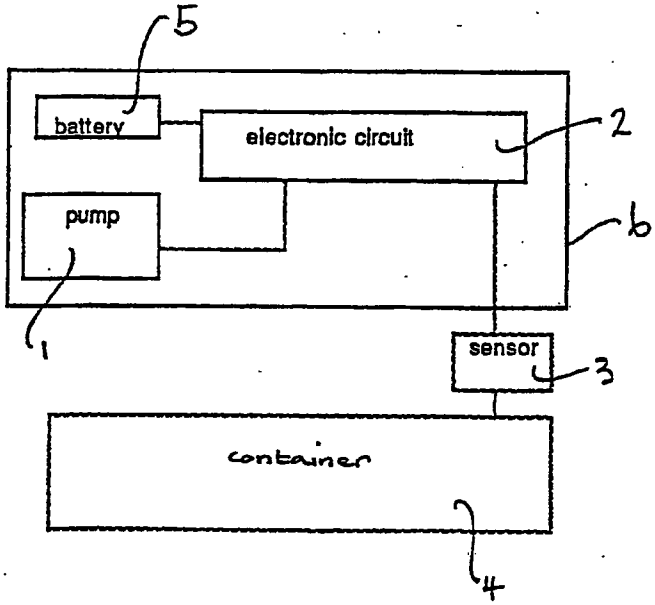
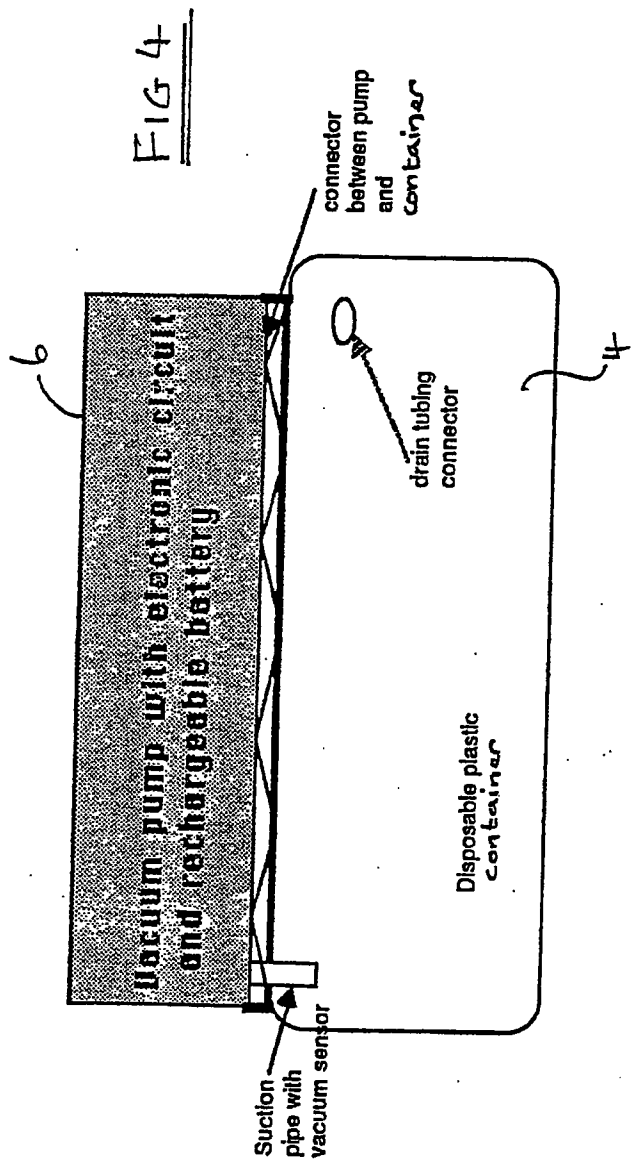


FIG 3

FIG 4


connector between pump and container
Vacuum pump with electronic circuit and rechargeable battery
drain tubing connector
Disposable plastic container
Suction pipe with vacuum sensor
6
4

CLOSED WOUND SUCTION APPARATUS

Field of the Invention:

This invention concerns improvements in and relating to closed wound suction apparatus for use in effecting proper drainage of a postoperative wound.

Background of the Invention:

Closed wound suction systems are known in which the suction that is applied to a drain tube inserted into a closed wound is achieved by means of a spring-loaded bellows device which is manually compressed before attachment to the drain tube and develops an internal suction pressure when the manual compression is released and the spring seeks to resile. One such closed wound suction system is the MaxiVac™ system that is available from Med General Laboratories Ltd. of Shannon Industrial Estate, Co.Clare, Ireland; this system aids in the maintenance of proper drainage of postoperative accumulation of serosanguineous fluid, purulent material and tissue debris in a wound, and at the same time decreases risk of infection, promotes primary wound healing and promotes the healing process by improving readaptation of tissue layers.

In common with other known closed wound suction

systems utilizing a spring-loaded bellows, the MaxiVac™ system suffers from the disadvantage that the suction that is produced by the bellows is at a maximum when first established and reduces thereafter. This causes uneven drainage of the wound, strong at the beginning and nil subsequently, which can give rise to clogging of the drainage tube. Additionally the vacuum that is generated cannot readily be modulated to the size and extent of the wound.

Objects and Summary of the Invention:

The principal object of the present invention is the provision of a closed wound suction apparatus which is not susceptible to the abovementioned disadvantages of known systems.

Another object of the present invention is to provide a closed wound suction apparatus enabling the suction pressure to be predetermined and maintained within set limits throughout a drainage period, and advantageously also enabling drainage progress to be monitored.

The above and other objects of the present invention are achieved by provision of a closed wound suction apparatus comprising an electrically operated vacuum pump coupled to a preferably disposable drainage collector coupled in turn to the wound

drainage tube, and wherein means are provided for monitoring and controlling the suction pressure in the drainage collector.

The apparatus according to the invention provides significant advantages in that the suction applied to a wound can be set by the surgeon, not only initially but also subsequently as healing progresses, and will thereafter be maintained so minimizing the need for constant progress checking and nurse intervention. Cost advantages may also be expected in that whilst the vacuum pump and associated controls are relatively expensive, the disposable drainage collector may be significantly less expensive than the bellows devices of such as the MaxiVac™ aforementioned so that over a period of time significant cost reductions may result.

The invention will best be understood from consideration of the following detailed description of an exemplary embodiment that is given with reference to the accompanying drawings.

Brief Description of the Drawings:

Figure 1 is a schematic showing of the variation in suction pressure that is achieved with a prior art device employing a spring-loaded bellows;

Figure 2 is a schematic showing of the suction pressure obtainable in accordance with the present invention;

Figure 3 is a block diagram showing of an exemplary embodiment of the present invention; and

Figure 4 is a general schematic showing of the embodiment.

Detailed Description of the Embodiment:

As has been explained in the foregoing, Figure 1 shows that the prior art spring-loaded bellows system provides and initial high vacuum level which reduces to zero over a period of time as the spring system of the bellows relaxes. The disadvantages of such prior art systems have been previously explained herein.

Figure 2 shows schematically how a closed wound suction apparatus may be programmed to operate within upper and lower vacuum values, with the electrically operated vacuum pump being switched on when the suction falls to the lower limit and being switched off when the suction rises to the upper limit. The difference between the upper and lower values can be set as desired and can even be reduced to zero or arranged to vary as a function of lapsed time.

Figure 3 is a schematic showing of an embodiment of the invention which comprises a battery operated miniature electric pump 1 coupled to an electronic circuit 2 which is arranged to be responsive to the condition of a pressure sensor 3 for controlling the pump operation within predetermined operator-set

levels. The pump 1 is coupled to a disposable drainage container 4 for determining the suction pressure therein, and the sensor 3 monitors the vacuum in the container 4. The container 4 in use is coupled to the wound drainage tube to receive substances drained from the wound. As shown in Figure 4 the pump 1 and associated electronic circuitry 2 and the battery 5 may be housed in a housing 6 having a suction pipe 7 and arranged to releasably couple with a disposable plastics container 4.

As has been previously stated herein, the apparatus according to the invention enables a customized vacuum to be set by the surgeon and will then automatically maintain such set vacuum, within predetermined and adjustable limits and optionally for a time period determined by the surgeon or dependent upon the rate of drainage from the wound that is achieved. Modern electronics and microprocessor facilities could if desired be utilized not only for control of the pump but also to monitor other sensors, such as sensors responsive to the quantity of drainage fluid in the container 4 and/or the rate of flow of drainage fluid, and to operate indicators and/or alarms in response thereto. The disposable drainage container 4 will ideally include self-sealing ports for connection to the suction pipe of the apparatus

and to the wound drainage tube so as to avoid leakage of possibly hazardous substances from a used drainage container awaiting incineration.

Monitoring of exudate volume and/or flow rate could be effected in a variety of different ways per se known in the art of liquid volume and flow monitoring. Non-contact methods are to be preferred for avoidance of risk of cross-contamination which could arise if, for example, re-usable probes were utilized for liquid level sensing. One preferred way of monitoring exudate volume and/or flow rate would be as a function of pump operation; the more frequently the pump has to be operated to maintain a set suction pressure the higher must be the exudate flow rate, and the integrated pump action likewise is an indicator of exudate volume. Where a re-usable drainage container, formed of glass or other autoclavable material for example, was used the exudate level within the container could be monitored by provision of sensor electrodes within the container, for example disposed on the container wall, or by optical or other techniques and the flow rate would be proportional to the rate of change of the level. Similar techniques per se known might be incorporated to enable the nature of the exudate to be monitored, for example as a function of its electrical conductivity.

The present invention thus provides a closed wound suction apparatus whereby a positive and constant suction pressure may be maintained by use of an electronically controlled vacuum pump coupled with an intelligent sensor programmable to the requirements of the particular postoperative condition being treated as determined by the surgeon. By use of microprocessor technology not only can the wound drainage program be set by the surgeon as required, but also the progress of wound drainage can be monitored to monitor exudate volume, flow and/or quality. The exudate container can be disposable and intended only to be used once in which case it should desirably include self-sealing ports, or can be re-sterilizable and re-usable.

CLAIMS:

1. A closed wound suction apparatus comprising an electrically operated vacuum pump, a drainage container coupled to the pump, a drainage tube coupled to the container and connectable into a wound to be drained, and a pressure sensor responsive to the suction pressure in the container for controlling the pump operation.

2. An apparatus as claimed in claim 1 wherein the vacuum pump is battery operated.

3. An apparatus as claimed in claim 1 or 2 wherein control means is provided enabling the operating suction pressure of the container to be set by an operator.

4. An apparatus as claimed in any preceding claim and including one or more further sensors responsive to fluid flow into said container.

5. An apparatus as claimed in any preceding claim wherein the container is disposable.

6. An apparatus as claimed in claim 5 wherein the container is self-sealing.

7. A closed wound suction apparatus substantially as herein described with reference to Figures 2,3 and 4 of the accompanying drawings.

(12) UK Patent Application (19) GB (11) 2 333 965 (13) A

(43) Date of A Publication 11.08.1999

(21) Application No 9909575.4

(22) Date of Filing 09.09.1998

Date Lodged 26.04.1999

(30) Priority Data
(31) 9719520 (32) 12.09.1997 (33) GB

(62) Divided from Application No 9819678.5 under Section 15(4) of the Patents Act 1977

(51) INT CL[6]
A61B 19/08

(52) UK CL (Edition Q)
A5R RED

(56) Documents Cited
GB 0692578 A US 5437622 A

(58) Field of Search
UK CL (Edition Q) A5R RED
INT CL[6] A61B 19/08

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(54) Abstract Title
SURGICAL DRAPE

(57) The invention relates to a surgical drape comprising a thin, flexible, adhesive-coated plastics film (21) and a strengthening layer (20) applied to the face opposite to the adhesive coating, the strengthening layer being a plastics film which is thicker or less flexible than said adhesive-coated film, and a protective, releasable layer (24) applied to the adhesive coating, the drape having an aperture through at least the strengthening film and adhesive-coated film to permit, in use, access to a wound area, at least one first edge of the drape having a non-adhesive coated handling bar (23) for separating the adhesive-coated film from the protective layer, and wherein the protective layer comprises a separate strip extending parallel to the first edge of the drape, and which protects the adhesive coating in the region of the aperture and carries at least one flap (27) overlapping the adjacent portion of the protective layer, said flap constituting a handle for facilitating removal of said strip prior to use.

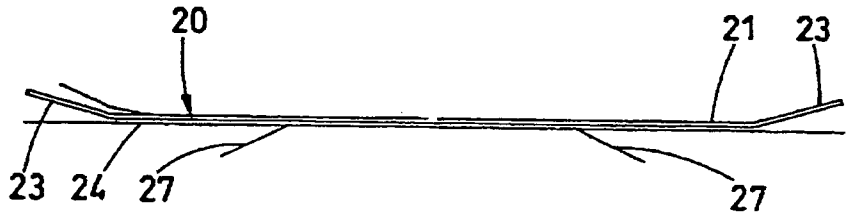

Fig. 3

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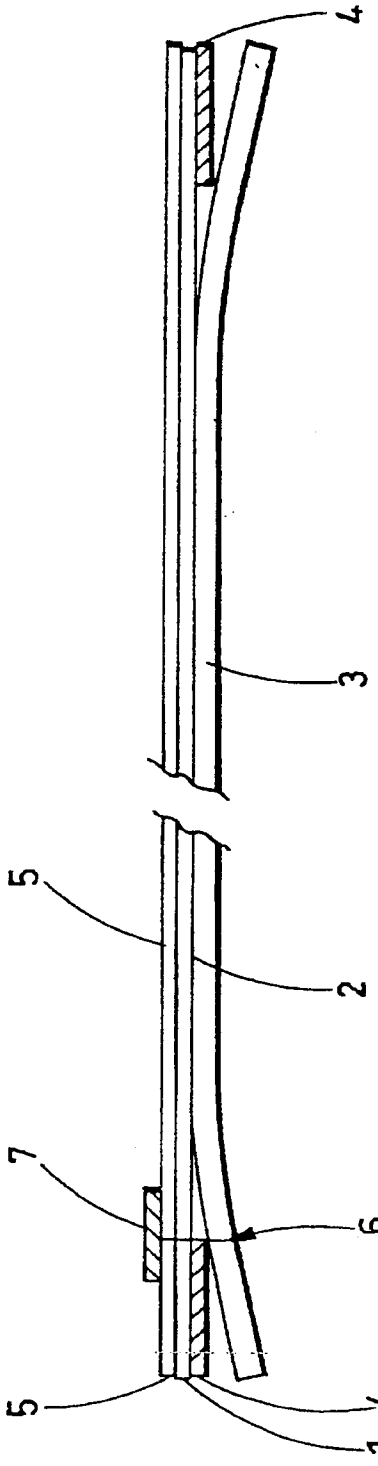

Fig.1

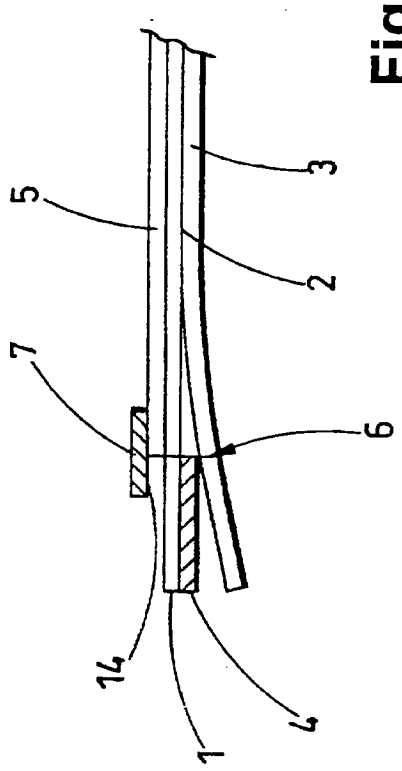

Fig. 2

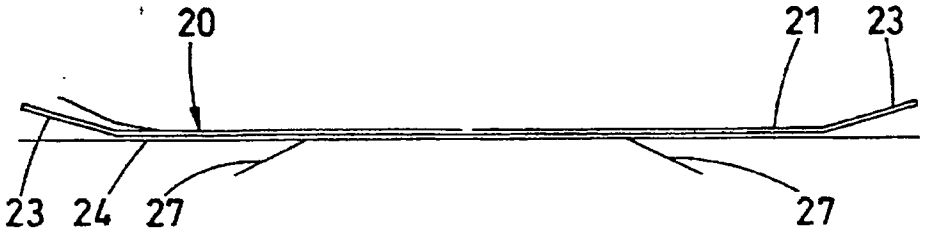

Fig. 3

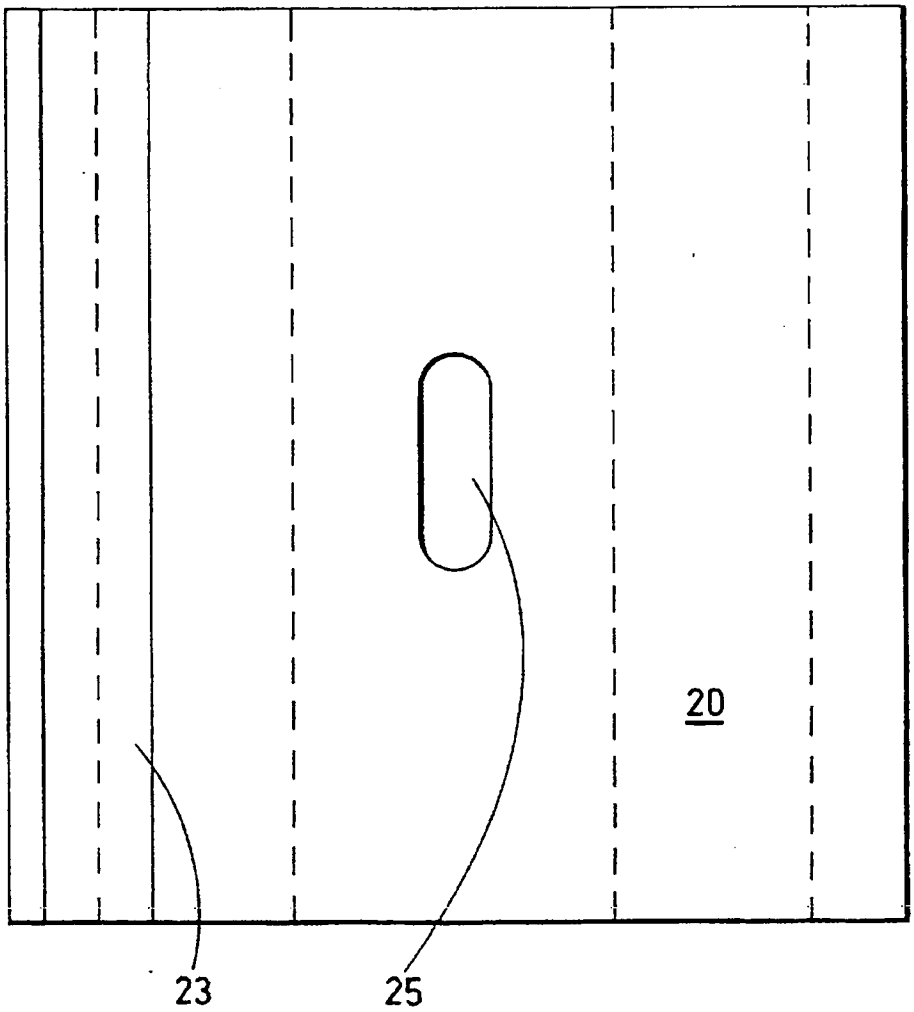

Fig. 4

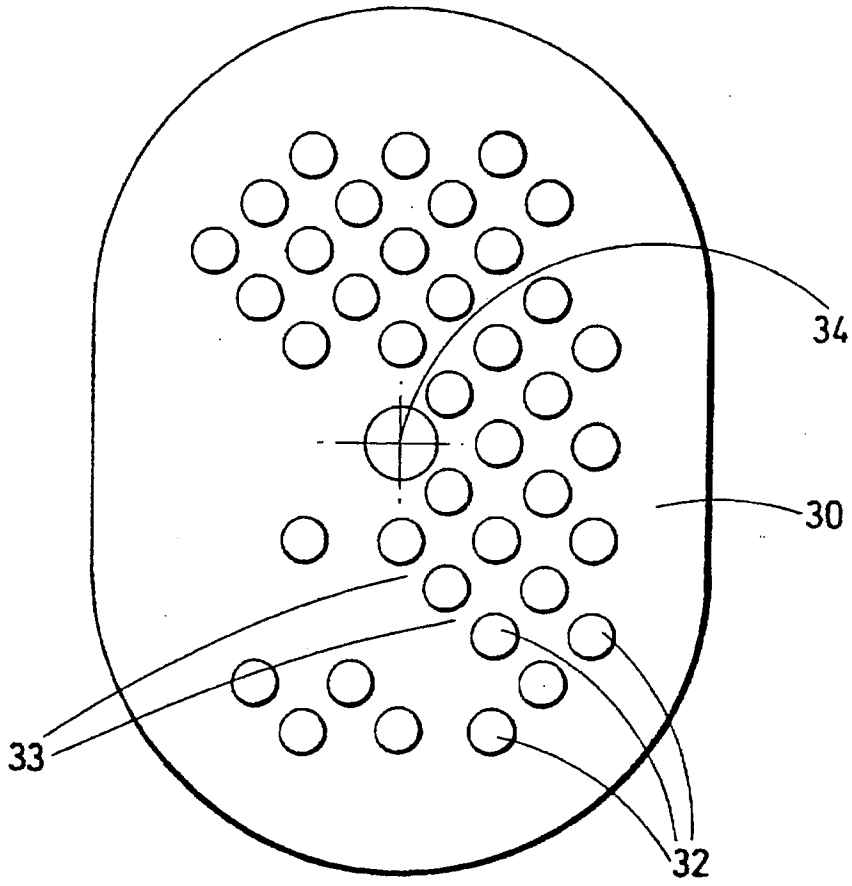

Fig. 5

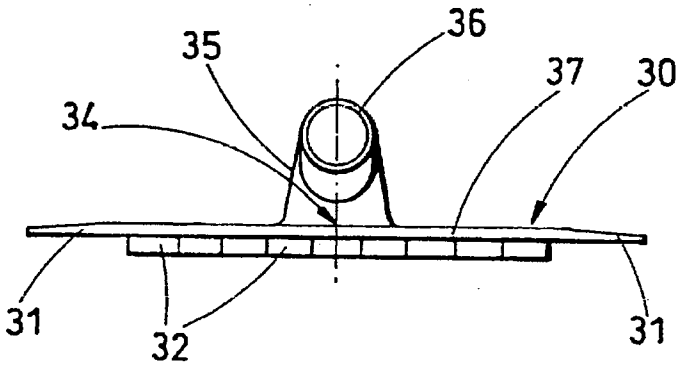

Fig. 6

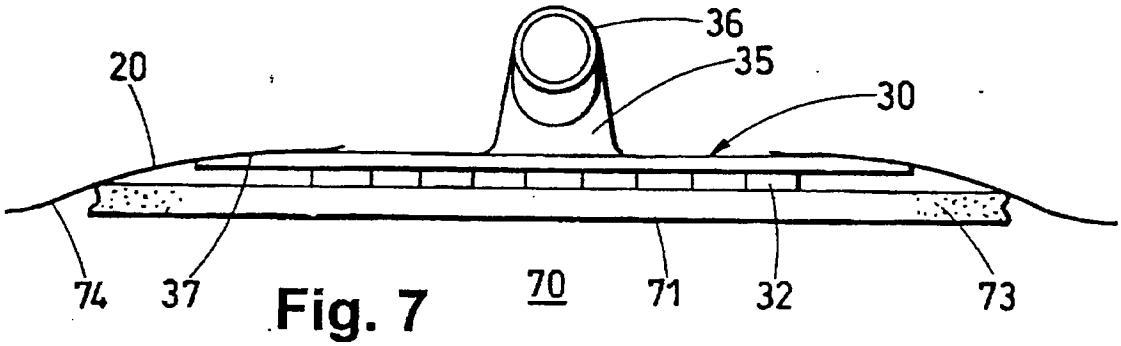

Fig. 7

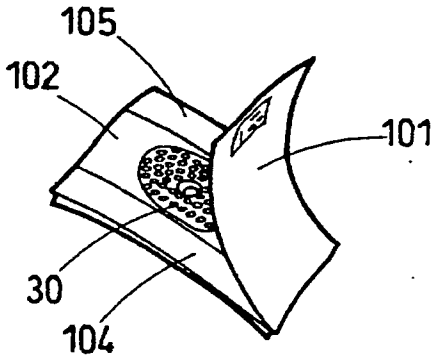

Fig. 8

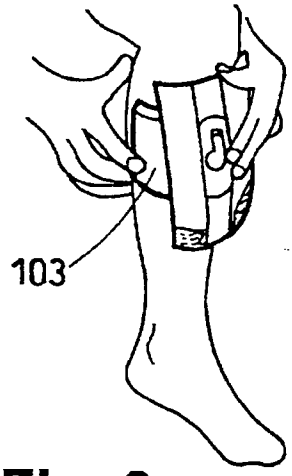

Fig. 9a

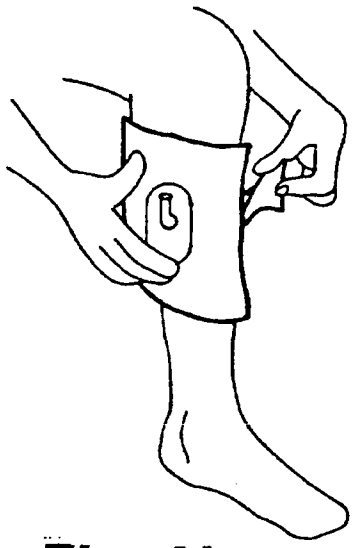

Fig. 9b

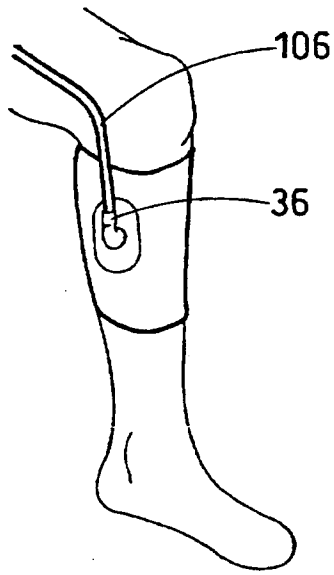

Fig. 9c

Surgical Drape and Suction Head for Wound Treatment

This invention relates to surgical drapes and suction heads for wound treatment.

Surgical drapes are widely used in surgical operations for the purpose of reducing infection and facilitating the handling of skin around incisions. Normally, they are transparent or translucent. Typically, they consist of a flexible, plastics film which is adhesive-coated and which is applied to the area of the operation, prior to making the incision. Surgical drapes are also used for attaching treatment devices to patients after an operation, such as catheters or drainage tubes.

A further, recently developed use is for connecting a suction tube to a wound for the purpose of stimulating healing of the wound. Such use is described in our earlier PCT Applications Nos. WO 96/05873 and WO 97/18007.

Various proposals have been made in the past to design the surgical drape so that handling of the sticky, flexible, plastics film is facilitated. For example, US Patent No. 5,437,622, describes a surgical drape which is a laminate of three materials. The first material comprising a transparent, thin plastics film which is adhesive-coated and this is protected with a layer of release-coated paper. The other face of the adhesive-coated film is strengthened with a reinforcing layer of a less flexible, plastics film. Handling bars or strips are attached to the flexible, plastics film at its lateral edges to facilitate handling of the flexible, plastics film after stripping away the protective releasable layer.

Where it is desired to use a surgical drape primarily to attach a device such as a catheter to a wound area after an operation or for long term treatment, it is inconvenient for the surgeon or nurse to have to adapt a standard surgical drape for this purpose. It would be more convenient to have a surgical drape which was suitable without adaptation to accommodate the treatment device.

One aspect of the present invention is directed to a solution to this problem. A second aspect provides a combined surgical drape and suction head for applying suction to a wound area to facilitate application of negative pressure therapy.

According to one aspect of the present invention there is provided a surgical drape which comprises a thin, flexible, adhesive-coated plastics film and a strengthening layer applied to the face opposite to the adhesive coating, the strengthening layer being a plastics film which is thicker or less flexible than said adhesive-coated film, and a protective, releasable layer applied to the adhesive coating, the drape having an aperture through at least the strengthening and adhesive-coated film to permit, in use, access to a wound area, a first edge of the drape having non-adhesive coated handling bars for separating the adhesive-coated film from the protective layer, and wherein the protective layer comprises a separate strip extending parallel to the first edge of the drape, and which protects the adhesive coating in the region of the aperture and carries a flap overlapping the adjacent portion of the protective layer, said flap constituting a handle for facilitating removal of said strip prior to use. Preferably, non-adhesive-coated handling bars are positioned at opposite lateral edges of the drape.

In practice, surgical drapes may be manufactured by laminating an adhesive-coated flexible film, such as a polyurethane film, to a protective releasable layer, such as a siliconised paper. A strengthening layer of thicker plastics material, e.g. a polyolefin such as polyethylene, may be applied to the non-adhesive coated face of the flexible film, so that a three-layer laminate is produced. These laminates are produced in substantial width and may be slit longitudinally to the desired width and then laterally to form drapes of the desired size.

After slitting to a desired width, handling bars are normally applied to the adhesive-coated layers at one or both lateral edges to facilitate separation of the film from the protective, releasable layer. While an aperture could be cut at the desired position through the layers to accommodate a catheter or a device such as those described in our above-mentioned applications, it is difficult to handle the highly pliable and adhesive film after the releasable layer has been stripped off.

Although the strengthening layer does somewhat improve the handling characteristics, this is not a complete answer to the problem. However, the handling

characteristics are substantially improved by providing a protective layer which is in at least two portions, one of which is in the form of a strip, e.g. one extending parallel to the lateral edges of the drape, and covering the peripheral area around the aperture through the drape. By providing a flap on this portion of the releasable layer, it can be stripped off initially so that the drape is first positioned around the device which is to pass through the aperture, and then the remaining part of the protective releasable layer is stripped off to adhere the drape to the patient's skin around the area to be treated.

In a preferred form of the invention in which negative pressure therapy is applied to a wound area, the surgical drape described above is combined with a suction head having a connector piece which is adapted to be connected to a suction tube. Thus, in this embodiment, the suction head can be adhered to the patient's skin in the area of the wound after removing the strip of protective releasable layer, and then the remaining part of the drape affixed to the patient's skin. In this way, the suction head is held firmly in place and, at the same time, seals the suction head to the wound area and prevents leakage of air from atmosphere into the wound area.

The invention also includes a suction head having a design which facilitates the suction of fluid from a wound area.

According to a further feature of the invention, therefore, there is provided a suction head for applying suction to a wound area which comprises a generally planar flange portion and a tubular connector piece on a first face, for connecting a suction tube to an aperture through the flange portion to the other face, said other face having projections defining flow channels facilitating flow of fluid towards said aperture.

Preferably, the suction head described above is combined with a surgical drape, the drape comprising a thin, flexible, adhesive-coated plastics film, and the tubular connector piece extends through an opening in the plastics film with the adhesive coating adhered to said first face of the flange portion.

Preferably, the suction head is used in conjunction with an open-celled foam pad so that one surface of the foam pad is placed in contact with a wound area and the

suction head applied to the other surface of the foam pad. In the case of deep wounds the foam may be shaped and placed so that it is packed into the wound cavity as described in our above cited PCT applications. According to another technique, which is particularly applicable to superficial wounds, the foam pad may be a relatively thin pad which is placed over the wound. The suction head is placed in contact with the open face of the foam pad and the drape applied over the suction head to fix the assembly to the patent's skin.

Various types of open celled foams can be used as described in our above cited PCT applications. The foam may be a polyurethane foam but polyvinyl acetate (pva) foams are preferred, especially when used as a pad which is placed over the wound. These are to some extent hydrophilic, which seems to exhibit beneficial comfort properties when applied to the skin. Wound healing is stimulated by maintenance of moist conditions in the wound area, and this is facilitated by using a hydrophilic foam.

Further features and advantages of the present invention will be apparent from the following description and accompanying drawings, of non-limiting examples in accordance with the invention.

Referring to the accompanying drawings:-

Figure 1 represents a conventional design of surgical drape;

Figure 2 represents a variation in the design of the handling bars at one end of the drape shown in Figure 1;

Figure 3 is a view similar to Figure 1 of a surgical drape in accordance with the invention;

Figure 4 is a plan view of the surgical drape shown in Figure 3;

Figure 5 is a plan view from beneath of a suction head in accordance with the invention; and

Figure 6 is a side elevation of the suction head shown in Figure 5;

Figure 7 is a view similar to Figure 6 but shows the suction head secured to a skin surface with the drape and with a foam pad located between the head and the skin surface.

Figure 8 is a perspective view of the drape with a central strip portion of the protective sheet in the course of being removed, and

Figures 9(a)–9(c) illustrate the steps of affixing the dressing assembly to a wound area on a patient's leg and attachment to a negative pressure assembly.

Referring to Figures 1 and 2 of the accompanying drawings, a conventional laminate for use as a surgical drape comprises a thin, flexible, transparent plastics film 1 which is adhesive-coated on one face 2, normally with a high-tack pressure-sensitive adhesive, and is protected with a releasable layer 3. The thin plastics film is conveniently of polyurethane because it transmits moisture. Layer 3 is normally considerably thicker than film 1 and is coated on the surface adjacent to the adhesive with a releasable material such as a silicone to facilitate stripping away from the adhesive-coated film.

In order to facilitate removal of the adhesive-coated film prior to use of the device, handling bars 4 are bonded at each end to the adhesive-coated film 1. Thus, by holding one of the bars 4, the protective layer 3 can be stripped off and the adhesive face applied to the skin of the patient. To facilitate handling of the thin, flexible film 1, a strengthening plastics film 5 is frequently applied to the free face of the plastics film 1. This is generally also transparent or translucent. Film 5 is preferably not bonded with adhesive to film 1, but may remain in contact by reason of electrostatic forces or because of close contact between the two conforming surfaces of film 1 and film 5.

Usually, the surgeon or nurse will wish to strip off the protective layer 5 after the film 1 has been correctly placed on the patient's skin, and this can be facilitated by making partial cuts 6 through the films 1 and 5, so that as the handling bar 4 is drawn upwards from the patient's skin, the adhesive film 1 remains adhered to the patient, while the partial cuts 6 causes separation of the flexible film from the strengthening film 5. Strengthening bars 7 may be provided to hold the lateral edges of the strengthening film 5 and film 1 together with their main parts.

An alternative arrangement is shown in Figure 2, in which the strengthening film 5 is provided with a separate overlapping handling bar 14, to facilitate its removal from the flexible film 1.

Further details of the make-up and manufacture of surgical drapes are given in US Patent No. 5,437,622 and European Patent Application No. 0161865 and the prior art referred to therein, the disclosure of which is incorporated herein.

Referring to Figure 3 and 4, the surgical drape of this invention comprises a protective outer film 20, laminated to a thin, flexible film 21. The flexible film 21 includes an adhesive-coated layer which is protected with a release-coated sheet material 24. Lateral edges of the flexible film 21 are provided with handling bars 23. Thus far, the design is essentially the same as that shown in Figures 1 and 2.

The drape of the present invention differs from the drape shown in Figures 1 and 2 in that an aperture 25 is cut through the strengthening layer 20 and through the flexible layer 21. The other difference compared with the prior art drapes is that the protective releasable layer is formed in at least two sections.

In the embodiments shown in Figures 3 and 4, the central portion of the releasable layer comprises a strip 26, having flaps 27 which overlap the remaining outboard portions of the releasable layer. The purpose of this is to enable the central strip 26 to be removed first, without disturbing the remaining portions of the releasable layer. The drape can then be fitted around the wound area and, if desired, a suction device or other treatment device passed through the aperture 25 and secured to the patient's skin with the peripheral areas of exposed adhesive-coated film.

An example of a device for applying suction to the wound area is illustrated in Figures 5, 6 and 7.

Referring to these Figures, the suction head comprises a flange portion 30 having a tapered edge 31, and a profile which may be of any desired shape but is generally rounded at its edges. On the face of the flange 30 intended for contact with the patient's skin or a foam pad are formed a series of projections 32 which are distributed over the surface of the flange apart from the peripheral edge portion 31.

The purpose of these projections is to provide fluid channels 33 facilitating the flow of fluids from any point of the flange to a central point 34, from which it is intended to apply suction. The suction head includes a connector 35, located above the aperture 34, having a tubular end 36 adapted for receiving and connecting a catheter. The tubular end may have an outwardly tapered portion to facilitate feeding a catheter into the connector. The upper surface 37 of the suction head has a substantially smooth surface.

In use, the connector portion 35 is sized so that it extends through the aperture 25 in the surgical drape shown in Figures 3 and 4, with the adhesive surface around the aperture bonded to the smooth surface 37 of the flange 30. The suction head may be packaged in this condition with the surgical drape so that in use, the strip 26 is removed by pulling on the handles 27 thus exposing the adhesive surface in the vicinity of and surrounding the suction head. The suction head can then fixed in the desired position on the patient's wound and then the remaining portion of the protective film removed to fix the drape to the patient. The flange 30 of the suction head may be somewhat oval as shown in Figure 5, and have dimensions as indicated in this Figure, i.e. a longer dimension of about 95mm and a short dimension of about 70mm. Alternatively, the flange may be circular and be smaller in plan view. For example, the diameter of a circular suction head may be from about 30 to 50mm in diameter, e.g. about 40mm. It has been found that the suction head flange should not overlap the area of the wound. Thus, in the case of smaller wounds a smaller suction head is indicated.

Figure 7 shows the suction head attached to a wound area 71 of a patient 70. The suction head is pressed into firm contact with a flexible, open-celled foam 73, which is itself pressed into contact with the wound area 71. The suction head and foam pad are pressed into contact with the wound area by a surgical drape 20 having an adhesive surface 74. The adhesive surface is bonded to the patient's skin outside the periphery of the foam pad and suction head. It is also bonded to upper surface 37 of the suction head. An aperture is formed in the drape to permit the connector

portion 35 to extend upwardly through the drape. In order to avert the danger of incorrect catheter tubes being fitted to the connector 35, the latter may have a customised cross-section or internal projection such as a rib or key which co-operates with a corresponding slot or key way in the catheter. Alternatively, the catheter may be moulded with a projection or longitudinal rib which co-operates with a corresponding slot or key way in the aperture of the connector 35.

The foam pad may be packaged in a plastic pouch, sterilised by gamma irradiation and supplied in the same box or in other packing units as the suction head and drape.

Figures 8 and 9(a)~(b) illustrate the way in which the drape/suction head combination is fitted to a wound on a patient's skin. In Figure 8, a backing sheet 101 having a release coated surface is removed in the first step from the adhesive face 102 of the drape to expose the face of the connector 30. A pad 103 of foam is positioned over the wound area and the drape placed over the foam paid, the drape being adhered to the skin above and below the pad (Figure 9a). The lateral protective strips 104 and 105 are removed in turn from the drape and the assembly adhered to the skin (Figures 9(b) and 9(c). Finally, the spout 36 is connected to a tube 106 which is then connected to a source of suction, e.g. a pump as described in our above PCT application, in order to apply negative pressure to the wound. The suction head and drape assembly is shown in Figure 8, with the smooth surface 37 adhered to the drape, is conveniently packaged in an easily openable plastic bag or pouch, and sterilised for immediate use.

CLAIMS:-

1. A surgical drape which comprises a thin, flexible, adhesive-coated plastics film and a strengthening layer applied to the face opposite to the adhesive coating, the strengthening layer being a plastics film which is thicker or less flexible than said adhesive-coated film, and a protective, releasable layer applied to the adhesive coating, the drape having an aperture through at least the strengthening film and adhesive-coated film to permit, in use, access to a wound area, at least one first edge of the drape having a non-adhesive coated handling bar for separating the adhesive-coated film from the protective layer, and wherein the protective layer comprises a separate strip extending parallel to the first edge of the drape, and which protects the adhesive coating in the region of the aperture and carries at least one flap overlapping the adjacent portion of the protective layer, said flap constituting a handle for facilitating removal of said strip prior to use.

2. A drape as claimed in claim 1 wherein the strengthening film comprises a polyolefin.

The Patent Office

INVESTOR IN PEOPLE

Application No: GB 9909575.4 **Examiner:** Mrs Susan Chalmers
Claims searched: 1-2 **Date of search:** 4 June 1999

Patents Act 1977
Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.Q): A5R: RED

Int Cl (Ed.6): A61B: 19/08

Other:

Documents considered to be relevant:

Category	Identity of document and relevant passage		Relevant to claims
A	GB 0692578	(MINNESOTA MINING) see especially page 1 lines 18-41, page 4 lines 38-59 and Figure 4	1
A	US5437622	(LABORATOIRE HYDREX) see especially column 2 lines 20-37 and Figure 1	1,2

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.